310-DD COVERED TRANSPLANTS AND RELATED IMMUNOSUPPRESSANT MEDICATIONS

EFFECTIVE DATE: October 1, 2019


This policy applies to the Division’s Administrative Services Subcontractors (AdSS). The Division contracts with AdSS and delegates the responsibility of implementing this policy.

Federal law 42 U.S.C. 1396b (i) and 42 CFR 441.35 describe general requirements for Title XIX coverage of transplants. For adults, organ transplant services are not mandatory covered services under Title XIX, and each state has the discretion to choose whether or not transplants will be available to members. The AHCCCS Administration, as the single state agency, has the authority under federal law to determine which transplant procedures, if any, will be reimbursed as covered services.

In contrast to transplant coverage for persons age 21 years and older, the Early and Periodic Screening Diagnostic and Treatment (EPSDT) Program for individuals under age 21 covers all non-experimental transplants necessary to correct or ameliorate defects, illnesses and physical conditions. Transplants members under age 21 eligible ALTCS Program are covered when medically necessary irrespective of whether or not the particular non-experimental transplant is specified as covered in the AHCCCS State Plan.

The Division covers the specific medically necessary transplantation services and related immunosuppressant medications as described in this policy.

The solid organ and tissue transplant services described in this policy, including the relevant standards of coverage, are referenced in the AHCCCS State Plan. The AHCCCS State Plan is the document approved by the federal government which outlines the eligibility requirements and covered services for the AHCCCS program.

Transplants must be medically necessary, cost effective, federally reimbursable, and state reimbursable. Arizona State laws and regulations specifically address transplant services and related topics, as follows:

A. Specific non-experimental transplants approved for Title XIX reimbursement are covered services (A.R.S. §36-2907).

B. Services which are experimental, or which are provided primarily for the purpose of research are excluded from coverage (A.A.C. R9-22-202).

C. Medically necessary is defined as those covered services “provided by a physician or other licensed practitioner of the healing arts within the scope of practice under state law to prevent disease, disability or other adverse health conditions, or their progression, or prolong life” (A.A.C. R9-22-101).

D. Experimental services are as described in R9-22-203.
E. Standard of care is defined as “a medical procedure or process that is accepted as treatment for a specific illness, injury or medical condition through custom, peer review or consensus by the professional medical community” (A.A.C. R9-22-101).

F. The AHCCCS Administration consulted with transplant experts to identify criteria for transplant coverage consistent with the current body of medical literature, including United Network for Organ Sharing (UNOS) clinical standards for solid organ transplant procedures, the Foundation for the Accreditation of Cellular Therapy (FACT) and peer-reviewed articles in medical journals published in the United States.

G. For persons ages 21 years and older, transplantation coverage is limited to the specific transplant types set forth in this policy. All other transplant types for persons ages 21 years and older are excluded from AHCCCS reimbursement. This policy includes criteria, indications and relative contraindications and absolute contraindications for each covered transplant type. Unless a contraindication is explicitly described as an absolute contraindication, the contraindication is a relative contraindication. However, these may change as a result of advances in medical treatment and technological innovation. The presence of an absolute contraindication precludes authorization for a transplant.

H. The AdSS must consult current authoritative medical sources to determine whether a transplant covered under this policy is medically necessary, cost-effective, non-experimental, and not primarily for purposes of research. The AdSS must provide the medical justification for the decision that is made. The AdSS has access to and may consult with the transplantation management entity (AHCCCS consultant) under contract with AHCCCS. Although the AdSS is encouraged to consult with the AHCCCS consultant for guidance in those cases requiring such medical determinations, the AdSS is not required to do so. AdSSs not using the AHCCCS consultant must obtain their own expert opinion.

Definitions

A. Absolute Contraindication – A condition or circumstance that if present precludes authorization of a transplant regardless of any other considerations.

B. Close Proximity - means within the geographic service area.

C. Emergent Fulminant Hepatic/Liver Failure - Liver failure that occurs suddenly in a previously healthy person. The most common causes are acute hepatitis, acetaminophen overdose, and liver damage from prescription drugs.

D. Experimental service – Refer to AHCCCS Rule R9-22-203. This rule provides, in part: Experimental services are not covered. A service is not experimental if:

1. It is generally and widely accepted as a standard of care in the practice of medicine in the United States and is a safe and effective treatment for the condition for which it is intended or used.

2. The service does not meet the standard in (1), but the service has been demonstrated to be safe and effective for the condition for which it is
intended or used based on the weight of the evidence in peer-reviewed articles in medical journals published in the United States.

3. The service does not meet the standard in (2) because the condition for which the service is intended or used is rare, but the service has been demonstrated to be safe and effective for the condition for which it is intended or used based on the weight of opinions from specialists who provide the service or related services.

E. Hematopoietic Stem Cell Transplants (HSCT) - The transplantation of blood stem cells derived from the bone marrow or peripheral blood, including cord blood. Conditioning therapy includes either myeloablative or non-myeloablative induction with or without Total Body Irradiation (TBI).

F. Relative Contraindications – A condition or circumstance that must be considered on a case-by-case basis to determine if a transplant will be authorized.

**Description of Policy**

This policy sets forth criteria, including indications and contraindications, for determining whether transplant services are medically necessary, cost effective, non-experimental, and not primarily for purposes of research. Contraindications are conditions which may significantly adversely impact the outcome of the transplant. They are not regarded as an absolute bar to transplantation. Contraindications must be evaluated along with all other relevant factors to determine whether the transplant service is medically necessary, non-experimental, and not primarily for purposes of research in each particular case.

The AdSS must consult with the Division’s Medical Director prior to denying the authorization for transplant of the heart, heart/lung, and liver.

**Transplant Services and Settings**

Transplant services are covered only when performed in specific settings:

A. Solid organ transplantation services must be provided in a CMS certified and UNOS approved transplant center which meets the Medicare conditions for participation and special requirements for transplant centers delineated in 42 CFR Part 482.

B. Hematopoietic stem cell transplant services must be provided in a facility that has achieved Foundation for the Accreditation of Cellular Therapy (FACT) accreditation. The facility must also satisfy the Medicare conditions of participation and any additional federal requirements for transplant facilities.

Transplantation related services and immunosuppressant drugs are not covered services for individuals in the Federal Emergency Services (FES) Program, pursuant to 42 U.S.C. 1396b(v)(3) and A.A.C. R9-22-206. Persons who qualify for transplant services, but who are later determined ineligible under A.R.S. 36-2907.10 due to excess income may qualify for extended eligibility (refer to AHCCCS Medical Policy 310-DD, Attachment A, Extended Eligibility Process/Procedure for Covered Solid Organ and Tissue Transplants).
Assessment for Transplant Consideration

The first step for transplant consideration is the initial assessment by the member’s Primary Care Provider (PCP) and/or the specialist treating the condition necessitating the transplant. In determining whether the member is appropriate for referral for transplant consideration, the PCP/specialist must determine that all of the following conditions are satisfied:

A. The member will be able to attain an increased quality of life and chance for long-term survival as a result of the transplant.

B. There are no significant impairments or conditions that would negatively impact the transplant surgery, supportive medical services, or inpatient and outpatient post-transplantation management of the member.

C. There are strong clinical indications that the member can survive the transplantation procedure and related medical therapy (e.g., chemotherapy, immunosuppressive therapy).

D. There is sufficient social support to ensure the member’s compliance with treatment recommendations such as, but not limited to, immunosuppressive therapy, other medication regimens and pre- and post-transplantation physician visits. For a pediatric/adolescent member, there is adequate evidence that the member and parent/guardian will adhere to the rigorous therapy, daily monitoring and re-evaluation schedule after transplant.

E. The member has been adequately screened for potential co-morbid conditions that may impact the success of the transplant. When the member’s medical condition is such that the evaluation must proceed immediately, the screenings may be provided by the PCP concurrent with the transplant evaluation.

F. The member’s condition has failed to improve with all other conventional medical/surgical therapies. The likelihood of survival with transplantation, considering the member’s diagnosis, age and comorbidities, is greater than the expected survival rate with conventional therapies. This information must be documented and submitted to the Division or the AdSS at the time of request for evaluation.

AHCCCS Covered Solid Organ and Hematopoietic Stem Cell Transplants

The Division covers solid organ and hematopoietic stem cell transplants covered services when medically necessary, cost effective, non-experimental, and not primarily for purposes of research. Live donor/kidney transplants are covered for pediatric and adult members.

Live donor transplants may be considered on a case-by-case basis for solid organs other than kidney when medically appropriate and cost effective. However, if a live donor transplant is approved for a non-kidney transplant, any costs related to the donor must not be separately reimbursed by AHCCCS or the Division, and no additional payment for the donor must be made unless the donor is AHCCCS eligible. Payment by AHCCCS and the Division for both the transplant recipient and the donor associated with non-kidney transplant services is limited to payment for the transplant and transplant-related services.
component during the 60-day post-transplant timeframe. Refer to the terms of the transplant contract for detailed information about coverage and payment for transplants and transplant-related services. For any additional charges, the living donor must accept the terms of financial responsibility for the charges associated with the transplant in excess of any payments under the transplant contract. Detailed criteria regarding specific transplants are found under the heading “Solid Organ and Related Devices: Specific Indications and Contraindications/Limitations.”

The following transplants are covered subject to the terms of this policy:

<table>
<thead>
<tr>
<th>Transplant Type</th>
<th>Covered For ALTCS Members * (Under Age 21)</th>
<th>Covered For Adult Members Eligible For ALTCS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Solid Organs</strong></td>
<td><strong>X</strong></td>
<td><strong>X</strong></td>
</tr>
<tr>
<td>Heart</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Lung (single and double)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Heart/Lung</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Liver</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Kidney (cadaveric and live donor)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Simultaneous Liver/Kidney (SLK)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Simultaneous Pancreas/Kidney (SPK)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Pancreas After Kidney (PAK)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Pancreas Only</td>
<td>X</td>
<td>Not Covered</td>
</tr>
<tr>
<td>Visceral Transplantation Intestine alone</td>
<td>X</td>
<td>Not Covered</td>
</tr>
<tr>
<td>Intestine with pancreas</td>
<td>X</td>
<td>Not Covered</td>
</tr>
<tr>
<td>Intestine with liver</td>
<td>X</td>
<td>Not Covered</td>
</tr>
<tr>
<td>Intestine, liver, pancreas en bloc</td>
<td>X</td>
<td>Not Covered</td>
</tr>
<tr>
<td>Partial pancreas (including islet cell transplants)</td>
<td>Not Covered</td>
<td>Not Covered</td>
</tr>
</tbody>
</table>

**Hematopoietic Stem Cell Transplants**

<table>
<thead>
<tr>
<th>Transplant Type</th>
<th>Covered For ALTCS Members * (Under Age 21)</th>
<th>Covered For Adult Members Eligible For ALTCS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allogeneic Related</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Allogeneic Un-related</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Autologous</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Tandem Hematopoietic Stem Cell Transplant (HSCT)</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

*All other medically necessary, non-experimental transplants for members under the age of 21 are covered.

Other transplants and devices included in this policy are:

A. Circulatory Assist Device (CAD) is a covered service when used as a bridge to
transplantation and other specific criteria are met. Refer to “Solid Organ Transplants
and Related Devices: Specific Indications and Contraindications/Limitations” within
this policy section for more details.

B. Bone grafts and corneal transplants are covered services.

Coverage of transplantation services includes the following, as required by the specific type
of transplant:

A. For the transplant candidate:

1. Donor search, human Leukocyte Antigens (HLA) typing, and harvest as
   necessary for stem cell transplants

2. Pre-transplant evaluation (inpatient or outpatient), which includes, but is not
   limited to:
   a. Physical examination
   b. Psychological and social service evaluations
   c. Laboratory studies
   d. X-ray and diagnostic imaging
   e. Biopsies

3. Pre-transplant dental evaluation and treatment of oral infection as described
   in Division Medical Policy 310-D, Exception for Transplant and Cancer Cases. Other
dental services, including, but not limited to, restorative and cosmetic
dentistry, will not be covered

4. Medically necessary post-transplant care (inpatient and outpatient), which
   may include, but is not limited to:
   a. Laboratory studies
   b. X-rays and diagnostic imaging
   c. Biopsies
   d. Home health
   e. Skilled Nursing Facility placement
   f. All related medications, including immunosuppressants

Note: The Division is the secondary payer of immunosuppressant
medications if the member is also a Medicare beneficiary and is
eligible to receive the immunosuppressant medications under
Medicare Part B. Drugs covered under Medicare Part D are not
covered for Division members eligible for Medicare whether or
not the member receives Medicare Part D coverage. Refer to Division Medical Policy 310-V, Prescription Medication/Pharmacy Services.

5. Transportation, room, and board for the transplant candidate and, if needed, one adult care giver as identified by the transplant facility, to and from medical treatment during the time it is necessary for the member to remain in close proximity to the transplant center. This includes the evaluation, ongoing testing, transplantation, and post-transplant care by the transplant center.

B. For the donor:

Services are covered only when provided in the United States and are limited to the following:

a. Evaluation and testing for suitability
b. Kidney donor procurement or stem cell procurement, processing and storage.
c. Transportation, room and board to determine if the donor is a match or to donate either stem cells or organs under the transplant recipient’s benefit.

Refer to the contract for detailed information regarding coverage and payment for transplants and transplant-related services. Transplants and transplant related services are limited to coverage through day 60 post-transplant surgery for non-kidney transplants or, in the case of kidney transplants, through day ten post kidney transplant. Complications for the transplant recipient or donor arising from the transplant surgery during the 60/10 post-transplant timeframe are considered transplant related and covered under the scope of the follow up care component(s).

Payment for the 60/10 follow-up care component represents payment for services for both the recipient and the donor, and no additional reimbursement must be made except as specified below for complications extending beyond the 60/10 timeframe.

Complications extending beyond day 60/10 are covered for the recipient if the recipient is AHCCCS eligible and the services are medically necessary and covered. Complications for the donor beyond day 60/10 are covered only if the donor is AHCCCS eligible at the time the complication arises and the services are medically necessary and covered.

**Contraindications for All Transplants**

Contraindications to solid organ and hematopoietic stem cell transplantation include, but are not limited to:

A. History of non-compliance or psychiatric condition(s) such that there is an inability to comply with post-transplant protocol

B. HIV positive status and viral load – members whose HIV status makes them ineligible for coverage of transplantation have the potential to seek transplant in one
of the National Institute of Health’s approved sites. These transplants are subject to the section of this described in the section of this policy entitled “Medically Necessary Services for Members who receive Transplants that are Not Covered.”

C. For solid organ transplants, active malignancy or prior metastatic malignancy within the past five years, other than localized cutaneous basal cell or squamous cell cancers, is an absolute contraindication. The five-year time frame for malignancy does not apply to liver transplants for hepatocellular carcinoma. For stem cell transplants, active or prior metastatic solid tumors malignancy within the past five years, other than localized cutaneous basal cell or squamous cell cancer, is a contraindication.

D. The failure of more than two organs. This does not include instances where the failure of one organ is secondary to the failure of another organ.

E. Presence of active uncontrolled infection or systemic infection (sepsis) at the time of transplant is an absolute contraindication.

F. Active substance abuse or history of substance abuse in the last six months (if there is an urgent need, evaluation may be allowed on a case-by-case basis).

G. Lack of a psychosocial support system, which, based on the member’s condition and general health, would place the success of the transplant at risk.

H. Non-adherence with previous or current treatment protocols that has resulted in the failure of a previously transplanted organ is a contraindication to re-transplantation.

**General Medical Conditions That Must Be Considered**

The general medical conditions that must be evaluated prior to transplant to determine whether a particular transplant is medically necessary, cost effective, non-experimental, and not primarily for purposes of research include, but are not limited to:

A. When a transplant consultation is requested, the AdSS will approve a drug and alcohol screen to be done at the requesting transplant center for all members 21 years of age and older.

B. For members with a history of substance abuse within the past three years, the member must provide a certificate of completion of a 12-month substance abuse program which has been approved by the Administration prior to determination for the transplant evaluation. For members with a history of substance abuse **greater than three years from the date of the transplant consultation request**, attendance in an approved substance abuse program may be waived. Members with a history of substance abuse **within the past three-year timeframe** must have a total of three consecutive negative random screens prior to the evaluation. In addition, the member will be monitored with random and repeated alcohol and drug screenings during the assessment process up to the time of the transplant. At the time of transplant evaluation, members with a history of substance abuse **within the prior three-year timeframe** must sign an agreement which states they will enroll in a post-transplant substance abuse program that will continue for a
continuous 12-month timeframe.

C. It is within the AdSS’s discretion to require a psychosocial assessment be completed prior to referral for transplant evaluation.

D. Any history of post-transplant substance abuse will exclude a member from further transplant procedures.

**Solid Organ Transplants and Related Devices: Specific Indications And Contraindications/Limitations**

**Heart Indications**

Prior to listing heart transplant, all other medical and/or surgical alternatives for correction and/or management of the underlying heart conditions(s) must either have been optimized or ruled out as a viable treatment option(s).

Criteria for medical necessity of heart transplantation include, but are not limited to, the following indications:

A. Left ventricular systolic dysfunction of any etiology

B. Valvular disease with left systolic dysfunction, unable to be surgically corrected

C. Congenital cardiac disease that has failed prior correction

D. Sarcoidosis

E. Drug-induced myocardial destruction due to prescription medication

F. Ischemic cardiomyopathy with a New York Heart Association Class III or IV cardiac disease when surgical or medical therapy is not likely to be effective and estimated survival is less than six to 12 months without a transplant.

G. Hypertrophic cardiomyopathy

H. Uncontrollable life-threatening arrhythmias

I. Refractory angina unresponsive to maximal medical and/or surgical therapy.

**Contraindications**

In addition to the contraindications noted in “Contraindication for All Transplants” section of this policy, the following are contraindications to heart transplantation:

A. Severe Pulmonary hypertension - inability to achieve Pulmonary Vascular Resistance (PVR) of <2.5 Wood units and/or a 15 mm Hg transpulmonary gradient on maximal medical therapy including vasodilators or inotropic medications; these patients may instead be candidates for heart-lung transplantation

B. Acute severe hemodynamic compromise at the time of transplantation if accompanied by compromise or failure of one or more vital end-organs
C. Recent (within past six months) intracranial vascular disease or prior stroke with severe deficits

D. Severe peripheral vascular disease unable to be corrected surgically

E. Chronic obstructive pulmonary disease or chronic bronchitis

F. Recent and/or unresolved pulmonary infarction or pulmonary embolus

G. The need for or prior transplantation of another organ such as lung, liver, kidney or hematopoietic transplants

H. Autoimmune diseases or collagen vascular diseases are relative contraindications depending on the disease, severity, and predicted lifespan

I. Insulin-dependent diabetes mellitus with end-organ disease (e.g., peripheral vascular/arterial disease, retinopathy, neuropathy, or nephropathy)

J. Active peptic ulcer disease

K. Chronic inflammatory bowel disease

L. Hepatic insufficiency

M. Amyloidosis

N. Age over 70

O. HIV positive

P. Morbid obesity with Body Mass Index (BMI) of 35 kg/m².

**Circulatory Assistive Device (CAD) Formerly Known As Ventricular Assist Devices (VAD) And Total Artificial Hearts (TAH)**

The Division covers Circulatory Assist Devices (CADs) that support heart function as a bridge to heart transplant only, for eligible members when medically necessary, cost effective, non-experimental, not primarily for purposes of research, and when the device is used in accordance with the Food and Drug Administration (FDA) approved labeling instructions.

For purposes of this policy, Circulatory Assist Devices are defined as VADS and Total Artificial Hearts (TAH). TAH may be used in lieu of bi-VAD when clinically appropriate and cost effective.

AHCCCS-contracted transplant center surgeons use their skill and judgment to select the appropriate assist device, based on all of the following:

A. Degree and presentation of cardiac insufficiency

B. Size of recipient
C. Device capability.

**CAD Criteria**

Medical necessity for CADs as a bridge to transplant is based on the following criteria:

**Adult Member**

The potential adult recipient must meet all of the following:

A. Is actively listed for cardiac transplantation

   Note: If a member is on the inactive transplant list due to a temporary medical complication (e.g., Status 7) and undergoes placement of a VAD or Total Heart, separate payment for those devices is only made if the patient returns to active status and is medically able to undergo a transplant should an organ become available. Medical records must indicate resolution of the temporary medical condition and show Active status for transplant with UNOS. If the patient never returns to active status, the device is not paid for separately, but payment continues to be made for medical management of the patient, and

B. Is experiencing end stage heart failure with progressive failure to respond to medical management and meets the definition of cardiogenic shock according to the New York Heart Association (NYHA) functional classification system.

**Pediatric Member**

The potential pediatric recipient must meet all of the following:

A. Is actively listed for cardiac transplantation

   Note: If a member is on the inactive transplant list due to a temporary medical complication (e.g., Status 7) and undergoes placement of a VAD or Total Heart, separate payment for those devices is only made if the patient returns to active status and is medically able to undergo a transplant should an organ become available medical records must indication resolution of the temporary medical condition and show active status for transplant with UNOS. If the patient never returns to active status, the device is not paid for separately, but payment continues to be made for medical management of the patient.

B. Age restrictions established by the FDA for the particular device used

C. Is in New York Heart Association class III or IV end-stage heart failure

D. Is refractory to medical therapy.
Contraindications

Contraindications to successful CAD placement and subsequent recovery include, but are not limited to:

A. Severe lung disease, except as appropriate for heart-lung transplantation (refer to the sections pertaining to lung and heart-lung transplantation in this policy)

B. Malignant disease

C. Stroke or refractory hypertension

D. Chronic pulmonary embolism or recent pulmonary infarction, except as appropriate for heart-lung transplantation (refer to the sections pertaining to lung and heart-lung transplantation in this policy)

E. Active infection

F. Irreversible disease of a major organ system, or

G. Critical psychosocial conditions, behaviors or problems in adherence to a disciplined medical regimen which preclude a positive transplant outcome.

Lung Indications

Criteria for medical necessity for lung transplantation include, but are not limited to, the following indications:

A. Alpha-1 antitrypsin deficiency

B. Primary pulmonary hypertension

C. Pulmonary fibrosis, idiopathic pulmonary fibrosis

D. Bilateral bronchiectasis

E. Cystic fibrosis (both lungs to be transplanted)

F. Bronchopulmonary dysplasia

G. Eisenmenger's syndrome

H. Sarcoidosis lung involvement

I. Scleroderma

J. Lymphangiomyomatosis

K. Eosinophilic granuloma

L. Pulmonary hypertension due to cardiac disease

M. Idiopathic fibrosing alveolitis.
Absolute Contraindications

In addition to the contraindications noted in “Contraindications for All Transplants” section of this policy, absolute contraindications to lung transplantation, include, but are not limited to:

A. Primary or metastatic malignancies of the lung
B. Colonization with highly resistant or highly virulent microorganisms
C. Untreatable, advanced dysfunction of any other organ (except the heart when a heart/lung transplant may be indicated)
D. Non-curable extra-pulmonary chronic infection
E. Inadequate biventricular cardiac function, significant coronary artery disease, or inadequate left ventricular function (these are not absolute contraindications if combined with a heart transplant)
F. System-wide involvement of cystic fibrosis
G. End Stage Renal Disease (ESRD)
H. Active tuberculosis.

Relative Contraindications

In addition to the absolute contraindications noted above, relative contraindications to lung transplantation, include, but are not limited to:

A. Acute respiratory insufficiency or failure requiring mechanical ventilation except adults with cystic fibrosis, where mechanical ventilation has not been shown to affect transplant survival
B. Abscess of lung and mediastinum
C. Significant chest wall and/or spinal deformity; prior thoracic surgery or other basis for pleural adhesions
D. Current significant acute illness that is likely to contribute to a poor outcome if the member receives a lung transplant
E. Chronic, incurable pulmonary infection in candidates for single lung transplantation
F. Continued cigarette smoking or failure to have abstained for a period of 12 months or longer.
G. Chronic cortisone therapy with more than 20 mg prednisone daily or recent therapeutic use of systemic steroids.
H. Severely limited functional status with low potential for rehabilitation
I. HIV positive
J. Active infection with Hepatitis B or C with a detectable viral load
K. Diabetes with end-organ dysfunction (e.g., peripheral vascular/arterial disease, retinopathy, neuropathy, or nephropathy)
L. Osteoporosis with vertebral collapse compression fractures
M. Age over 65
N. Hepatic insufficiency
O. Morbid obesity with 30 kg/m².

**Heart and Lung Indications**

Criteria for medical necessity for heart/lung transplantation include, but are not limited to, the following indications:

A. Irreversible primary pulmonary hypertension with congestive heart failure
B. Non-specific pulmonary fibrosis
C. Eisenmenger’s complex with irreversible pulmonary hypertension and heart failure
D. Cystic fibrosis with severe heart failure
E. Emphysema with severe heart failure
F. Chronic Obstructive Pulmonary Disease (COPD) with severe heart failure.

**Contraindications**

Refer to the individual heart and lung sections in this policy for contraindications.

**Liver**

Timing of referral:

Prior to referral to a transplant center for evaluation, the AdSS must calculate the adult member’s Model for End stage Liver Disease (MELD) score. An adult member must have a MELD score greater than 10 to meet criteria for referral.

The AdSS must calculate the pediatric member’s Pediatric End stage Liver Disease (PELD) score prior to transplant evaluation. The PELD score automatically assigns additional points for a child.

**Indications for Adult and Pediatric Liver Transplants**

Criteria for medical necessity for liver transplantation in adults and pediatric liver transplants (except as otherwise indicated) include, but are not limited to, the following indications:
A. Fulminant hepatic failure – This is an emergent basis for transplant (viral [A, B and Non-A-Non-B], toxins, drugs, Wilson’s Disease, Idiopathic)

B. Primary/secondary biliary cirrhosis

C. Primary sclerosing cholangitis

D. Cryptogenic or autoimmune cirrhosis

E. Chronic active hepatitis due to Hepatitis B, C or delta hepatitis

F. Alcoholic liver disease after a period of abstinence of six months or more

G. Alpha-1 antitrypsin deficiency (non-acquired)

H. Wilson’s Disease

I. Primary hemochromatosis

J. Protoporphyria

K. Familial Intrahepatic Cholestasis (Byler’s disease)

L. Trauma

M. Drug-or toxin-induced liver disease (including but not limited to iatrogenic origin)

N. Extrahepatic biliary atresia, intrahepatic bile duct paucity (Alagille syndrome), and obstructive biliary disease

O. Budd-Chiari syndrome

P. Biliary dysplasia

Q. Metabolic liver disorders

R. Cholangiocarcinoma (for adults: when a transplant center applies for a MELD exception for unresectable cholangiocarcinoma based on underlying liver disease or due to technical considerations, mass < 3 cm. and with intrahepatic and extrahepatic metastases excluded)

S. Hepatocellular Carcinoma (HCC) when all of the following conditions are met:
   1. The member is not a candidate for subtotal liver resection
   2. The member has a single tumor less than or equal to 5 cm in diameter or up to 3 lesions each smaller than 3 cm
   3. There is no macrovascular involvement or identifiable extrahepatic spread of tumor to surrounding lymph nodes, lungs, abdominal organs or bones, and
   4. This is not a recurrence of previous resected or treated HCC.
T. Re-transplantation when any of the following occurs:

1. Chronic rejection with documented adherence to the post-transplant protocols
2. Biliary stricture
3. Hepatic artery thrombosis
4. Graft thrombosis
5. Sickle cell hepatopathy
6. Hepatic veno-occlusive disease
7. Reinfection with the Hepatitis C virus following a liver transplant is an absolute contraindication to re-transplantation.

**Additional Indications Limited to Pediatric Transplants**

Criteria for medical necessity for liver transplantation limited to the pediatric population include, but are not limited to, the following indications:

A. Intractable cholestasis, intrahepatic (idiopathic neonatal hepatitis)
B. Portal hypertension
C. Multiple episodes of ascending cholangitis
D. Failure of synthetic function
E. Failure to thrive, malnutrition
F. Intractable ascites
G. Encephalopathy
H. Caroli’s with Congestive Heart Failure (CHF)
I. Cystic fibrosis
J. Metabolic defects for which liver transplantation will reverse life threatening illness and prevent irreversible Central Nervous System (CNS) damage; the following may be underlying diagnoses/disorders that lead to pediatric liver transplantation:

1. Urea cycle defects
2. Selected organic acidemias
3. Crigler-Najjar Syndrome
4. Familial hypercholesterolemia
5. Neonatal iron storage disease
6. Hyperoxaluria Type I
7. Hemophilia A and B
8. Tyrosinemia
9. Glycogen storage disease (I, III, IV)
10. Glycogen debrancher deficiency 1B
11. Disorders of bile acid metabolism
12. Lipid storage disease, and
13. Protein C Deficiency

K. Malignancy including but not limited to:
   1. Hepatoblastoma
   2. Hepatocellular carcinoma
   3. Hemangioendothelioma
   4. Sarcomas, and
   5. Neuroendocrine tumors when the tumor does not extend beyond the margins of the liver.

Contraindications Limited to Adults

In addition to the contraindications noted in the "Contraindications for All Transplants" section of this policy, contraindications to liver transplantation in adults, include, but are not limited to:

A. Malignancies, other than Hepatocellular Carcinoma (HCC) with the criteria previously stated in this section
B. Acute severe hemodynamic compromise at the time of transplant if accompanied by compromise or failure of one or more vital organs
C. The need for prior transplantation of another organ such as lung, kidney, heart or blood or marrow if this represents a coexistence of significant disease
D. Insulin-dependent diabetes mellitus with end-organ disease
E. Gross vascular invasion of hepatocellular carcinoma
F. Systemic diseases that will result in member death regardless of liver transplant
G. Morbid obesity with BMI >35 kg/m².
Contraindications Limited to Pediatric Liver Transplants

In addition to the contraindications noted in the “Contraindications for All Transplants” section of this policy, contraindications to liver transplantation in the pediatric population include, but are not limited to:

A. Persistent viremia
B. Active sepsis
C. Severe cardio-pulmonary comorbidities
D. Severe neurological disorder
E. Gross vascular invasion of hepatocellular carcinoma
F. Malignancy extending beyond the margins of the liver with exception of neuro-endocrine tumors metastatic into the liver
G. Systemic diseases that will result in member death despite liver transplant.

Kidney Indications

Criteria for medical necessity for live donor or cadaveric kidney transplantation includes, but is not limited to, and or all of the following indications:

A. All dialysis or advanced chronic kidney disease patients are transplant candidates until deemed unsuitable for transplant. Transplant is usually indicated when Glomerular Filtration Rate (GFR) falls below 20 ml/min,
B. When the onset of dialysis is expected in the next six months (pre-emptive transplant).
C. Symptomatic uremia at GFR above 20 ml/min.

Indications Limited to the Pediatric Population

For pediatric kidney transplants, additional criteria for transplantation include, but are not limited to:

A. Wilm’s tumor (non-metastatic)
B. Oxalosis (may also require a liver-kidney transplant and will be considered on a case-by-case basis)

Contraindications

In addition to the contraindications noted in the “Contraindications for All Transplants” section of this policy, contraindications to kidney transplantation include, but are not limited to any of the following:

A. Potential complications from immunosuppressive regimens that are unacceptable to
the member (the benefits of remaining on dialysis outweigh the risks of transplantation)

B. Structural problems, or abnormalities with the lower urinary tract, which interfere with normal renal function of the transplanted kidney

C. Severe cardiomyopathy or ischemic heart disease that is not correctable

D. Cardiac ejection fraction <30%

E. Hepatic cirrhosis

F. Diffuse, pronounced vascular disease that is not correctable

G. Active peptic ulcer disease

H. Any chronic medical condition besides chronic kidney dysfunction where life expectancy is less than two years

I. Morbid Obesity with BMI > 35 kg/m².

**Living Kidney Donor Exclusion Criteria**

A. To qualify as a living kidney donor, the donor must be at least 18 but not more than 65 years of age and must be able to give informed consent.

B. In addition, the donor will not be considered if he/she has any of the following:

1. Hypertension (>140/90 or requires medication)
2. Diabetes or abnormal glucose intolerance test
3. Proteinuria >250 mg/24 hours
4. Recent or recurrent kidney stones
5. Donors with a history of familial kidney disease such as Alport Syndrome, polycystic kidney disease, and nephrotic syndrome must be assessed for risk
6. Abnormal glomerular filtration rate, creatinine clearance <80 mL/min
7. Microscopic hematuria
8. Structural abnormalities in donor kidney
9. History of prior malignancy other than cutaneous squamous or basal cell cancer
10. Significant co-morbid medical conditions (e.g., malignancy, COPD)
11. Obesity (with BMI >35 kg/m²)
12. History of thrombosis or thromboembolism
13. Psychiatric contraindications including active substance abuse.

**Simultaneous Liver/Kidney (SLK)**

Timing of referral:

A. Prior to referral to a transplant center for evaluation, the AdSS must calculate the adult member’s Model for End stage Liver Disease (MELD) score. An adult member must have a MELD score greater than 10 to meet criteria for referral.

B. The Contractor must calculate the pediatric member’s Pediatric End stage Liver Disease (PELD) score prior to transplant evaluation. The PELD score automatically assigns additional points for a child.

**Indications for Simultaneous Liver/Kidney Transplants**

Refer to the individual liver and kidney sections in this policy for indications and general medical considerations.

**Contraindications for Simultaneous Liver/Kidney Transplants**

Refer to the individual liver and kidney sections in this policy for contraindications and general medical considerations.

**Simultaneous Pancreas/Kidney (SPK)**

Indications for Simultaneous Pancreas/Kidney (SPK) Transplantation

Criteria for medical necessity for simultaneous pancreas/kidney transplantation include, but are not limited to, the following indications:

A. Insulin-dependent diabetes mellitus with impending renal failure, and

B. The member is an acceptable candidate for pancreas transplantation

**Contraindications**

In addition to the general contraindications noted in the “Contraindications for All Transplants” section of this policy, contraindications to SPK include, but are not limited to, any of the following:

A. Uncorrectable cardiovascular or peripheral vascular disease

B. Cardiac ejection fraction < 30%

C. Peripheral vascular disease that is not correctable

D. Active substance abuse

E. End-organ disease, in other than pancreas or kidney, secondary to insulin-dependent diabetes mellitus
F. Morbid obesity with BMI >30 kg/m².

**Pancreas After Kidney (PAK)**

For members under age 21 eligible for the ALTCS Program, covered services are limited to total pancreas only after kidney transplant. Partial pancreas and islet cell transplantation are not covered for both members under 21 and member’s age 21 years and older.

**Indications for Pancreas After Kidney Transplantation**

Criteria for medical necessity of pancreas after kidney transplantation include, but are not limited to:

A. Achievement of adequate renal function post kidney transplantation

B. Extreme labile Type I diabetes that has not responded to conventional therapy including an insulin pump.

**Contraindications**

In addition to the general contraindications noted in the “Contraindications for All Transplants” section of this policy, contraindications to pancreas after kidney transplantation include, but are not limited to:

A. Uncorrectable cardiovascular or peripheral vascular disease

B. Cardiac ejection fraction < 30%

C. Peripheral vascular disease that is not correctable

D. Active substance abuse

E. End-organ disease, in other than pancreas or kidney, secondary to insulin-dependent diabetes mellitus

F. Morbid obesity with BMI >30 kg/m².

**Pancreas Only**

Pancreas-only transplants are limited to members under age 21 eligible for the ALTCS Programs when the member meets the criteria below.

A. Documented pancreas organ failure

B. Documented medically uncontrollable labile insulin-dependent diabetes mellitus with documented recurrent, severe, acutely life-threatening metabolic complications that require frequent (three or more emergency room visits or hospital admissions in a three-month period) hospitalization

C. Hospitalizations related to complications due to frequent hypoglycemia unawareness or recurring severe ketoacidosis, or recurring hypoglycemic attacks, and
D. Management by an endocrinologist for a minimum of 12 months with the most medically recognized advanced insulin formulations and delivery systems, including insulin pump therapy if appropriate.

Note: For individuals age 21 and older, AHCCCS covers pancreas after kidney and simultaneous pancreas/kidney transplants. Pancreas-only transplants are not a covered benefit for adults unless the member has previously had a Pancreas After Kidney transplant or Simultaneous Pancreas/Kidney transplant and the pancreas is failing.

**Visceral Transplants**

A. Visceral transplantation is limited to members who are under 21 years of age and meet the medical eligibility criteria.

B. Cadaveric en bloc visceral transplants involving pancreas/liver/small bowel are covered when clinically indicated.

**Indications For Members Under Age 21 Eligible For The ALTCS Program**

Criteria for visceral transplantation alone, and combined small bowel/liver/ pancreas transplantation in any combination include, but are not limited to the following conditions:

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 any of the following:
   1. Intestinal cysts
   2. Mesenteric cysts
   3. 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])

D. Impending or overt liver or pancreas failure due to TPN-induced liver injury, with clinical manifestations including elevated serum bilirubin and/or liver enzymes, splenomegaly, thrombocytopenia, gastroesophageal varices, coagulopathy, stomal bleeding or hepatic fibrosis/cirrhosis

E. Thrombosis of two or more major central venous channels (jugular, subclavian or femoral veins)
F. Two or more episodes per year of systemic sepsis secondary to line infection, which require hospitalization, indicating failure of TPN therapy

G. Frequent episodes of severe dehydration despite intravenous fluid supplement in addition to TPN

H. Gastrochisis.

**Contraindications for Members Under Age 21 Eligible for the ALTCS Program**

In addition to the general contraindications noted in the “Contraindications for All Transplants” section of this policy, contraindications to visceral transplantation include, but are not limited to, the following conditions:

A. Insufficient vascular patency

B. Life-threatening and non-correctable illness not related to the digestive system such as:
   1. Profound neurological disability
   2. Chronic cardio-pulmonary disease.

**Hematopoietic Stem Cell Transplants (HSCT)**

Hematopoietic Stem Cell Transplant (HSCT) is the transplantation of blood stem cells derived from the bone marrow or blood, including cord blood. Conditioning therapy includes either myeloablative or non-myeloablative induction with or without Total Body Irradiation (TBI).

Medical necessity for Cord Blood Transplantation (CBT) in adults will be determined on a case-by-case basis. For any pediatric CBT, a single cord blood unit will be considered standard treatment.

**Autologous HSCT**

Criteria for medical necessity for autologous HSCT include, but are not limited to, any of the following indications:

A. Adults
   1. Acute Myelogenous Leukemia (AML) in remission
   2. Chronic Myelogenous Leukemia (CML) in remission
   3. Relapsed Hodgkin Lymphoma that is chemosensitive
   4. Mantle cell lymphoma that is chemosensitive
   5. Germ cell tumors (tandem)
   6. Multiple myeloma (tandem)
7. Amyloidosis in patients with adequate organ function
8. Waldenstrom’s macroglobulinemia
9. Non-Hodgkin lymphoma subtypes where peer-reviewed data has confirmed safety and efficacy of the proposed transplant procedure.

B. Pediatric
1. Neuroblastoma (tandem appropriate if done per a clinical trial)
2. Medulloblastoma
3. Brain tumors, other than medulloblastoma, including central nervous system germ cell tumors, Peripheral Neuro-Ectodermal Tumor (PNET), atypical Teratoid/Rhabdoid Tumor (AT/RT), oligodendroglioma, and pineoblastoma, where peer-reviewed data on safety and efficacy for the proposed transplant procedure have been successfully demonstrated
4. Relapsed chemo-sensitive Non-Hodgkin lymphoma
5. Other pediatric solid tumors (Wilm’s tumor, Ewings sarcoma, etc.) where peer-reviewed data on safety and efficacy for the proposed transplant have been successfully demonstrated.

Whether a specific disease meets the criteria for autologous HSCT is determined by current guidelines as published by specialty societies such as the American Society for Blood and Marrow Transplantation (ASBMT) and the Children’s Oncology Group (COG).

**Contraindications**

In addition to the general contraindications noted in the “Contraindications for All Transplants” section of this policy, contraindications to Autologous HSCT include, but are not limited to, the any of the following conditions:

A. Evidence of cirrhosis or significant liver dysfunction, since this can be a factor for development of Sinusoidal Obstruction Syndrome (SOS) formerly called Veno-Occlusive Disease (VOD)

B. Uncontrolled, progressive or active systemic infection at the time of transplant is an absolute contraindication. Prior infection, or infection where there is relative control with a post-transplant plan of control, is not an absolute contraindication and must be considered on a case-by-case basis

C. Prior malignancy, other than disease being treated by transplant, within the last five years. These must be considered on a case-by-case basis

D. Cystic fibrosis (absolute) and other multi-system disease not correctable by hematopoietic stem cell transplantation
E. End-organ damage of either heart or lungs

F. Parenchymal brain disease that raises the risk of cerebrovascular hemorrhage

G. Prior allogeneic hematopoietic stem cell transplant is a relative contraindication depending on disease responsiveness, disease control, patient’s performance status, and presence of other co-morbidities. These must be considered on a case-by-case basis.

**Allogeneic HSCT**

Criteria for medical necessity for Allogeneic HSCT include, but are not limited to, the following indications:

A. Adults

1. Acute Myelogenous Leukemia
   a. Primary indication failure or slow to induce or refractory disease
   b. In first complete remission, if patient at moderate risk for relapse per standard criteria and a match, related donor is available
   c. In first complete remission, if patient at high-risk for relapse per standard criteria and has either a match, related donor or a well-matched unrelated donor available
   d. In second complete remission

2. Acute Lymphogenous Leukemia, in remission

3. Chronic Myelogenous Leukemia
   a. Unresponsive to tyrosine kinase inhibitor control with three prior lines of therapy
   b. Intolerance to tyrosine kinase inhibitors or has severe side effects
   c. Accelerated phase or blast crisis

4. Relapsed or progressive Hodgkin lymphoma that is chemosensitive

5. Relapsed or progressive large cell Non-Hodgkin lymphoma that is chemosensitive

6. Chemosensitive low-grade or follicular Non-Hodgkin lymphoma when clinical evidence indicates transformation to more aggressive subtype (Richter transformation)

7. Relapsed or progressive Non-Hodgkin lymphoma that is chemosensitive and there is peer-reviewed data demonstrating both safety and efficacy for the particular NHL subtype involved
8. Myelodysplastic Syndrome with acceptable donor (either a matched, related donor or well, matched, unrelated donor)

9. Fanconi Anemia

10. Other Hematological Disorders for which peer-reviewed data on safety and efficacy for proposed transplant have been successfully demonstrated including, but not limited to:
   a. Sickle cell disease
   b. Severe congenital anemia
   c. Thalassemia.

B. Pediatric

1. Acute Myelogenous Leukemia

2. Juvenile Myelomonocytic Leukemia, at any stage, with any donor type

3. Chronic Myelogenous Leukemia
   a. Unresponsive to tyrosine kinase inhibitor control (usually three prior lines of therapy)
   b. Intolerance to tyrosine Kinase inhibitors,
   c. Accelerated phase or blast crisis

4. Acute Lymphogenous Leukemia
   a. In first complete remission, if high-risk for relapse; or primary indication failures who subsequently achieve a first complete remission
   b. T-cell Acute Lymphogenous Leukemia in first complete remission with early marrow relapse (<six months)
   c. In the second complete remission, if early relapse (less than 36 months remission)

5. Relapsed or progressive Hodgkin Lymphoma that is chemosensitive

6. Relapsed or progressive Non-Hodgkin Lymphoma that is chemosensitive, and there is peer-reviewed data demonstrating safety and efficiency of the proposed procedure for the particular Non-Hodgkin Lymphoma subtype involved

7. Inborn errors of Metabolism in patients who have not yet suffered either significant or irreversible end-organ damage

Example Indications:
- Hurler syndrome
- Sly syndrome (MPSVII)
- D-Mannosidosis
- X-linked Adrenoleukodystrophy
- Aspartylglucosaminuria
- Wolman disease
- Late infantile metachromatic leukodystrophy
- Krabbe disease

8. Primary lethal immune deficiencies and hemophagocytic lymphohistiocytosis such as:
   a. Wiskott-Aldrich Syndrome,
   b. Severe combined immune deficiencies (SCID), and

9. Fanconi Anemia

10. Other Hematological Disorders for which peer-reviewed data on safety and efficacy for the proposed transplant have been successfully demonstrated, including but not limited to:
   a. Sickle cell disease,
   b. Severe congenital anemia
   c. Thalassemia.

**Contraindications**

In addition to the contraindications noted in the “Contraindications for All Transplants” section of this policy, contraindications to allogeneic HSCT include, but are not limited to, the following conditions:

A. Evidence of cirrhosis or severe liver dysfunction
B. Cystic fibrosis is an absolute contraindication
C. Uncontrolled, progressive or active systemic infection at the time of transplant is an absolute contraindication
D. End-organ damage of either heart or lungs
E. Parenchymal brain disease that poses a risk for cerebrovascular hemorrhage
F. Prior hematopoietic stem cell transplant is a relative contraindication depending on
disease responsiveness, disease control, patient’s performance status, and presence of other co-morbidities. These must be considered on a case-by-case basis.

**Out-Of-Network Coverage**

The AdSSs must provide out-of-network coverage for solid organ or hematopoietic stem cell transplants for those members who have current medical requirements that cannot be met by an appropriate in-network transplant center. These medical requirements must be manifested as requiring either a specific level of technical expertise or program coverage that is not currently provided by an AHCCCS contracted facilities. A request for out-of-network coverage will not be approved if the member has already received a medical denial from an AHCCCS contracted transplant center. The use of out-of-network transplant centers is determined by the review of quality and outcome data, as published by center’s accreditation organization, and the center’s cost containment standards.

When a member completes a Division approved transplantation at an out-of-network facility, the necessary follow-up services will be covered through an AHCCCS contracted in-network facility, if one is available. These services include, but are not limited to, travel, lodging, meals, medical testing and post-operative evaluation and apply to any transplant performed under AHCCCS coverage, another third-party payer or through self-pay.

**Multiple Site Listing For Solid Organ/Hematopoietic Transplantation**

If a member seeks to be evaluated for solid organ, or hematopoietic stem cell transplantation and is "listed" with more than the primary AHCCCS contracted transplant center, the Division will only pay for one center’s evaluation services.

If a member becomes listed by a facility other than the primary AHCCCS contracted transplant center, the Division will not provide coverage for any costs in excess of the state-contracted rate for the specific transplant procedure.

In addition, reimbursement will be available only to FACT accredited or UNOS approved facilities. Facilities must be CMS certified transplant centers and must meet the Medicare conditions of participation and the special requirements for transplant centers set forth in 42 CFR Part 482.

If a member chooses to make his/her own arrangements for travel, lodging and/or meals, the member must notify the AdSS of the arrangements they have made. In addition, the member, in such circumstances, is responsible for securing and sending appropriate medical records to the appropriate transplant case manager.

**Non-transplant Medically Necessary Services Covered by AHCCCS for Members Who Receive Non-covered Transplants**

If a member receives a transplant that is not covered by the Division, medically necessary, non-experimental services commence following discharge from the acute care hospitalization for the transplant.

A. Covered services include, but are not limited to:

a. Transitional living arrangements appropriately ordered for post-transplant
members when the member does not live in close proximity to the center

b. Essential laboratory and radiology procedures
c. Medically necessary post-transplant therapies
d. Immunosuppressant medications
e. Medically necessary transportation.

B. Covered services do not include:
   a. Evaluations and treatments to prepare for transplant candidacy
   b. The actual transplant procedure and accompanying hospitalization
   c. Organ or tissue procurement.

Division reimbursement of the AdSS for medically necessary services following non-covered organ transplantation is in accordance with the regular reinsurance guidelines found in the AHCCCS Reinsurance Processing Manual as adopted by the Division. Division-covered transplantation and its related medically necessary services are reimbursed in accordance with the transplant reinsurance guidelines found in the Reinsurance Processing Manual, with the exception of kidney transplants, cornea transplants and bone grafts. These services are covered as part of regular capitation payments and any related services may be covered in accordance with the regular reinsurance guidelines.

**Transplantation Management**

The AHCCCS Administration has entered into a contract with a transplantation management entity (consultant) to review developments, outcomes and respective changes in technology, and assist in the development and revision of this policy. The consultant will be available, as necessary, to provide expertise regarding clinical issues arising from transplant requests.

Although the AdSS is encouraged to consult with the transplantation management entity (AHCCCS consultant) under contract with AHCCCS for guidance in making medical determinations regarding transplants. The AdSS is not required to use the AHCCCS consultant in reaching its medical determination. The AdSS may obtain its own expert opinion. A written medical justification for the AdSS’s decision is required in each case.

AHCCCS, in partnership with the consultant, is available to assist with questions and issues concerning specific diagnoses and medical conditions that are covered for transplantation.

Consultation may include, but is not limited to:

A. Telephone access to the Consultant Medical Director. Access will be arranged by the DHCM Medical Management Unit

B. Regular updates on changes in experimental status of selected transplants and advances in technology and devices
C. Analysis of transplantation and related technology developments with enough information, including cost projections, to assist AHCCCS in revising this policy as necessary

D. Assistance in recommendation of approved/appropriate transplant facilities, as necessary, for out-of-network coverage.