

## **310-DD - COVERED TRANSPLANTS AND RELATED IMMUNOSUPPRESSANT MEDICATIONS**

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### **I. PURPOSE**

This Policy applies to ACC, ACC-RHBA, ALTCS E/PD, DCS CHP (CHP), and DES DDD (DDD) Contractors; Fee-For-Service (FFS) Programs including: American Indian Health Program (AIHP), Tribal ALTCS; and all FFS populations, excluding Federal Emergency Services Program (FESP). Transplantation related services and immunosuppressant medications are not covered services for individuals in the FESP, pursuant to 42 USC 1396b(v) and AAC R9-22-206. This Policy establishes AHCCCS coverage requirements for transplants and related immunosuppressant medications.

### **II. DEFINITIONS**

Refer to the [AHCCCS Contract and Policy Dictionary](#) for common terms found in this Policy.

### **III. POLICY**

#### **A. COVERED TRANSPLANTS**

The Federal law 42 USC 1396b(i) and 42 CFR 441.35 describe general requirements for Title XIX coverage of transplants. For individuals age 21 and older, organ transplant services are not mandatory covered services under Title XIX and States have discretion to choose whether transplants will be covered for members age 21 years and older.

For members ages 21 years and older, AHCCCS limits transplantation coverage to the specific transplant types set forth in this Policy. All other transplant types for members 21 years and older are excluded from AHCCCS reimbursement.

Under the Early and Periodic Screening Diagnostic and Treatment (EPSDT) Program for persons under age 21, AHCCCS covers all non-experimental transplants necessary to correct or ameliorate defects, illnesses, and physical conditions. Transplants for EPSDT members are covered when medically necessary irrespective of whether the particular non-experimental transplant is specified as covered in the AHCCCS State Plan.

Table one summarizes coverage for EPSDT-age members and adult members age 21 years and older by transplant type. AHCCCS utilizes national standards for transplantation which include policy from Organ Procurement Transplant Network (OPTN), Centers for Medicare and Medicaid Services (CMS), United Network for Organ Sharing (UNOS), and the Foundation for the Accreditation of Cellular Therapy (FACT).

Additional Arizona State laws and regulations that specifically address transplant services and related topics are as follows:

1. The specific non-experimental transplants which are approved for Title XIX reimbursement are covered services (ARS 36-2907 and 2939).
2. The services which are experimental, or which are provided primarily for the purpose of research are excluded from coverage (AAC R9-22-202, R9-22-203, R9-28-201, R9-28-202).
3. The 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” (AAC R9-22-101, R9-28-101).
4. The Transplants shall be medically necessary, non-experimental, Federally reimbursable, State reimbursable, and fall within the medical standard of care for coverage. The 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” (AAC R9-22-101, R9-28-101).

**TABLE 1: AHCCCS COVERED TRANSPLANTS**

TRANSPLANT TYPE	COVERED FOR EPSDT MEMBERS (UNDER AGE 21) *	COVERED FOR ADULT MEMBERS (AGE 21 AND OLDER)
<b>SOLID ORGANS</b>		
Heart	X	X
Lung (single and double)	X	X
Heart/Lung	X	X
Liver (cadaveric)	X	X
Liver (living)	X	
Kidney (cadaveric and living donor)	X	X
Simultaneous Liver/Kidney	X	X
Simultaneous Pancreas/Kidney	X	X
Pancreas after Kidney	X	X
Pancreas only	X	Not Covered
Visceral Transplantation <ul style="list-style-type: none"> <li>• Intestine alone</li> <li>• Intestine with pancreas</li> <li>• Intestine with liver</li> <li>• Intestine, liver, pancreas en bloc</li> </ul>	X	X

TRANSPLANT TYPE	COVERED FOR EPSDT MEMBERS (UNDER AGE 21) *	COVERED FOR ADULT MEMBERS (AGE 21 AND OLDER)
<b>SOLID ORGANS</b>		
Partial pancreas (including islet cell transplants)	X	Not Covered
<b>HEMATOPOIETIC STEM CELL TRANSPLANTS</b>		
Allogeneic Related	X	X
Allogeneic Unrelated	X	X
Autologous	X	X
Tandem Hematopoietic Stem Cell Transplant	X	X
*All other medically necessary, non-experimental transplants for members under the age of 21 are covered.		

The Circulatory Assist Devices (CADs) including Left Ventricular Assist Devices (LVADs) are AHCCCS covered services for destination therapy and as bridge to transplant when medically necessary and non-experimental.

The Transplants are reimbursed through the AHCCCS Reinsurance process and the [AHCCCS Specialty Contract for Transplantation Services](#). The Kidney transplants, corneal transplants, and bone grafts are AHCCCS covered services but not covered under the AHCCCS Specialty Contract.

All transplants must be medically necessary, cost effective, and non-experimental.

Refer to the AHCCCS Specialty Contract for Transplantation Services and the [AHCCCS Reinsurance Policy Manual](#) on the AHCCCS website for detailed information regarding coverage and payment for transplants and transplant-related services.

For questions regarding transplant authorizations coverage and general inquires contact AHCCCS Medical Management at [medicalmanagement@azahcccs.gov](mailto:medicalmanagement@azahcccs.gov). For FFS PA requirements refer to AMPM Policy 820.

The Persons who qualify for transplant services, but who are later determined ineligible under ARS 36-2907.10 due to excess income, may qualify for extended eligibility (refer to Attachment A).

**B. COVERED TRANSPLANT SERVICES**

The coverage of transplantation services by component includes the following, as required by the specific type of transplant, refer to the [AHCCCS Specialty Contract for Transplantation Services](#) and the [AHCCCS Reinsurance Policy Manual](#):

1. For the transplant candidate:
  - a. A Pre-transplant evaluation (inpatient or outpatient), which includes, but is not limited to, the following:
    - i. A Physical examination,
    - ii. A Psychosocial evaluation,
    - iii. Laboratory studies,
    - iv. A Pre-transplant dental evaluation and treatment as specified in AMPM Policy 310-D1 under “Exception for Transplant Cases”,
    - v. X-ray and diagnostic imaging, and
    - vi. Biopsies.
  - b. A Donor search, Human Leukocyte Antigen (HLA) typing, and harvest as necessary for hematopoietic transplants,
  - c. A Transplantation,
  - d. Post-transplant care (inpatient and outpatient), which may include, but is not limited to, the following:
    - i. Laboratory studies,
    - ii. X-rays and diagnostic imaging,
    - iii. Biopsies,
    - iv. Home health,
    - v. Skilled Nursing Facility (SNF) services, and
    - vi. All related medications, including immunosuppressants. Refer to AMPM Policy 310-V, Prescription Medication/Pharmacy Services for more information related to AHCCCS medication coverage.
  - e. Transportation, room, and board for the transplant candidate, donor and, if needed, one adult caregiver, 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.
2. For the donor:

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

  - a. Evaluation and testing for suitability,
  - b. Solid organs or hematopoietic stem cell procurement, processing, and storage, and
  - c. Transportation and lodging when it is necessary for potential donors to travel for testing to determine if they are a match and to donate either stem cells or organs.

Refer to the AHCCCS Specialty Contract for Transplantation Services on the AHCCCS website for a more detailed description of transplant services for the member and donor that include pre-transplant evaluation, donor search, organ/tissue harvesting or procurement, preparation and transplantation services, and convalescent care.

**C. CONDITIONS FOR TRANSPLANTATION**

1. The OPTN policies set the criteria for wait listing for organ transplantation. Transplant candidates shall meet the criteria to be waitlisted based on OPTN policy.
2. The Medical comorbidities shall be assessed through history and physical with plans developed for appropriate care. The changes in medical conditions (cardiovascular, development of new malignancy, etc.) shall be assessed for impact upon transplant candidacy. All candidates shall undergo routine age-condition appropriate screening for disease.
3. The psychosocial environment shall be assessed by a Behavioral Health Professional (BHP). Appropriate plans should be generated to mitigate issues of adherence to the treatment plan. For members with prior adherence issues, an adherence plan shall be developed.
4. For members with Substance Use Disorder(s) (SUDs), plans for treatment before and after the transplant shall be demonstrated in agreement with a BHP or an appropriate health care professional.

**D. TRANSPLANT SERVICES AND SETTINGS**

The Transplant services, including evaluation, are covered only when performed in specific settings:

1. The solid organ transplant services shall 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.
2. The Hematopoietic stem cell transplant services shall be provided in a facility that has achieved FACT accreditation. The facility shall also satisfy the Medicare conditions of participation and any additional Federal requirements for transplant facilities.

**E. ADDITIONAL INFORMATION AND REQUIREMENTS**

1. AHCCCS provides 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 AHCCCS contracted transplant center. These medical requirements shall be manifested as requiring either a specific level of technical expertise or program coverage that is not currently provided by AHCCCS contracted facilities. The selection of an out-of-network transplant center is determined through the review of quality and outcome data published.

2. The reimbursement shall only be available for transplant centers who meet requirements in Section D of this Policy.
3. The financial responsibility of AHCCCS and its Contractors for solid organ living donor-related costs is limited to pediatric kidney and liver transplants and adult kidney transplants. Living donor transplants may be considered on a case-by-case basis for solid organs other than kidney (pediatrics and adults) and liver (pediatric only) when medically necessary and cost effective. Payment by AHCCCS and its Contractors for the solid organ donor other than kidney (pediatrics and adults) and liver (pediatric only) is limited to surgical and follow-up care provided to the donor through and including day three post-surgery. For any additional charges, the living donor shall accept the terms of financial responsibility for the charges associated with the transplant in excess of any payments under the AHCCCS Specialty Contract for Transplantation Services.
4. If a member receives a transplant that is not covered by AHCCCS, coverage for medically necessary and non-experimental services commence following discharge from the acute care hospitalization for the non-covered transplant:
  - a. The covered services include, but are not limited to:
    - i. The transitional living arrangements are appropriately ordered for post-transplant members when the member does not live in close proximity to the center,
    - ii. The Essential laboratory and radiology procedures,
    - iii. The Medically necessary post-transplant therapies,
    - iv. Immunosuppressant medications as specified in AMPM Policy 310-V, Prescription Medication/Pharmacy Services for more information related to AHCCCS medication coverage, and
    - v. The Medically necessary transportation.
  - b. The covered services do not include:
    - i. Evaluations and treatments to prepare for transplant candidacy,
    - ii. The actual transplant procedure and accompanying hospitalization, or
    - iii. Organ or tissue procurement.

Refer to [AHCCCS Specialty Contract for Transplantation Services](#) and the [AHCCCS Reinsurance Policy Manual](#) on the AHCCCS website for information regarding a second covered organ transplant performed during the follow up care periods of the first transplant.

Refer to the AHCCCS Reinsurance Processing Manual for information regarding Contractor applications for transplantation reinsurance.