

310-DD COVERED TRANSPLANTS AND RELATED IMMUNOSUPPRESSANT MEDICATIONS

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11/01/06, 06/01/05, 06/01/04, 09/01/03, 07/01/99, 01/16/20**I. PURPOSE**

This Policy applies to ACC, ALTCS E/PD, DCS/CMDP (CMDP), DES/DDD (DDD), and RBHA Contractors; Fee-For-Service (FFS) Programs including: American Indian Health Program (AIHP), Tribal ALTCS; and all FFS populations, excluding Federal Emergency Services (FES). Transplantation related services and immunosuppressant medications are not covered services for individuals in the FES Program, pursuant to 42 U.S.C. 1396b(v) 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 Attachment A). This Policy outlines AHCCCS coverage for transplants and related immunosuppressant medications.

II. DEFINITIONS**BEHAVIORAL HEALTH
PROFESSIONAL
(BHP)**

1. An individual licensed under A.R.S. Title 32, Chapter 33, whose scope of practice allows the individual to:
 - a. Independently engage in the practice of behavioral health as defined in A.R.S. §32-3251, or
 - b. Except for a licensed substance abuse technician, engage in the practice of behavioral health as defined in A.R.S. §32-3251 under direct supervision as defined in A.A.C. R4-6-101,
2. A psychiatrist as defined in A.R.S. §36-501,
3. A psychologist as defined in A.R.S. §32-2061,
4. A physician,
5. A behavior analyst as defined in A.R.S. §32-2091,
6. A registered nurse practitioner licensed as an adult psychiatric and mental health nurse; or
7. A registered nurse with:
 - a. A psychiatric-mental health nursing certification, or
 - b. One year of experience providing behavioral health services.

**ORGAN PROCUREMENT
AND TRANSPLANTATION
NETWORK
(OPTN)**

Established through the National Organ Transplant Act (NOTA), OPTN is a public-private partnership operated through U.S. Department of Health and Human Services. The OPTN policies govern operation of all member transplant hospitals, Organ Procurement Organizations (OPOs) and histocompatibility labs in the United States.

**UNITED NETWORK FOR
ORGAN SHARING
(UNOS)**

Private, non-profit organization that manages the nation's organ transplant system under contract with Organ Procurement and Transplantation Network (OPTN), including managing the national transplant waiting list and maintaining database that contains all organ transplant data for every transplant event that occurs in U.S.

**FOUNDATION FOR THE
ACCREDITATION OF
CELLULAR THERAPY
(FACT)**

A non-profit corporation co-founded by the International Society for Cellular Therapy (ISCT) and the American Society of Blood and Marrow Transplantation (ASBMT) for the purposes of voluntary inspection and accreditation in the field of cellular therapy.

WAITING LIST

As defined by OPTN, a computerized list of candidates who are waiting to be matched with specific deceased donor organs for transplant.

III. POLICY**A. COVERED TRANSPLANTS**

Federal law 42 U.S.C. §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 or not 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 medically necessary to correct or ameliorate defects, illnesses and physical conditions. Transplants for EPSDT members are covered when medically necessary irrespective of whether or not 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. Transplants shall be medically necessary, non-experimental, and federally reimbursable, State reimbursable, and fall within the medical standard of care for coverage. 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, R9-28-101). 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 specifically address transplant services and related topics are as follows:

1. Specific non-experimental transplants which are approved for Title XIX reimbursement are covered services (A.R.S. §§36-2907 and 2939).
2. Services which are experimental, or which are provided primarily for the purpose of research are excluded from coverage (A.A.C. R9-22-202, R9-22-203, R9-28-201, R9-28-202).
3. 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, 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)
SOLID ORGANS		
Heart	X	X
Lung (single and double)	X	X
Heart/Lung	X	X
Liver	X	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"> • Intestine alone • Intestine with pancreas • Intestine with liver • Intestine, liver, pancreas en bloc 	X	Not Covered
Partial pancreas (including islet cell transplants)	X	Not Covered
HEMATOPOIETIC STEM CELL TRANSPLANTS		
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.*

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.

Corneal transplants and bone grafts are covered when medically necessary cost effective, and non-experimental as specified in AMPM Exhibit 300-1 and AMPM Policy 820.

Refer to the AHCCCS Specialty Contract For Transplantation Services 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/DHCM, Medical Management at medicalmanagement@azahcccs.gov.

B. COVERED TRANSPLANT SERVICES

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

1. For the transplant candidate:
 - a. Pre-transplant evaluation (inpatient or outpatient), which includes, but is not limited to, the following:
 - i. Physical examination
 - ii. Psychosocial evaluation
 - iii. Laboratory studies
 - iv. X-ray and diagnostic imaging, and
 - v. Biopsies
 - b. Donor search, HLA typing, and harvest as necessary for hematopoietic transplants.
 - c. Pre-transplant dental evaluation and treatment as described in AMPM Policy 310-D1 under “Exception for Transplant Cases.”
 - d. Transplantation
 - e. 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 services
 - vi. All related medications, including immunosuppressants. Refer to AMPM Policy 310-V, Prescription Medication/Pharmacy Services for more information related to AHCCCS medication coverage.

- f. Transportation, room, and board for the transplant candidate, donor 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.
2. 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. Solid organ or hematopoietic stem cell procurement, processing, and storage.
 - c. Transportation and lodging when it is necessary for potential donor 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. OPTN policies set the criteria for wait listing for organ transplantation. Transplant candidates shall meet the criteria to be wait listed based on OPTN policy.
2. Medical comorbidities shall be assessed through history and physical with plans developed for appropriate care. 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. Identified indolent or chronic infections shall have a plan of containment in accord with an infectious disease specialist.
4. Members with identified neoplasms shall be assessed in accord with an oncologist.
5. The psychosocial environment shall be assessed, and appropriate plans generated to mitigate issues of adherence. For members with prior adherence issues, plans with a Behavioral Health Professional shall be developed.
6. For members with substance use disorder(s), plans for treatment before and after the organ replacement shall be demonstrated in agreement with a Behavioral Health Professional.

D. TRANSPLANT SERVICES AND SETTINGS

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

1. Solid organ transplant services shall be provided in a Centers for Medicare & Medicaid Services (CMS) certified and United Network for Organ Sharing (UNOS) approved transplant center which meets the Medicare conditions for participation and special requirements for transplant centers delineated in 42 CFR Part 482.
2. Hematopoietic stem cell transplant services shall be provided in a facility that has achieved Foundation for the Accreditation of Cellular Therapy (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 must 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. Reimbursement will 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 3 post surgery. 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 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. Covered services include, but are not limited to:

- i. Transitional living arrangements appropriately ordered for post-transplant members when the member does not live in close proximity to the center
 - ii. Essential laboratory and radiology procedures
 - iii. Medically necessary post-transplant therapies
 - iv. Immunosuppressant medications (Refer to AMPM Policy 310-V, Prescription Medication/Pharmacy Services for more information related to AHCCCS medication coverage.)
 - v. Medically necessary transportation
 - b. 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
5. Refer to AHCCCS Specialty Contract for Transplantation Services on the AHCCCS website for information regarding a second covered organ transplant performed during the follow up care periods of the first transplant.
6. Refer to the AHCCCS Reinsurance Processing Manual for information regarding Contractor applications for transplantation reinsurance.