

310-DD COVERED TRANSPLANTS AND RELATED IMMUNOSUPPRESSANT MEDICATIONS

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REFERENCES: A.R.S. §36-2907, 2939; A.A.C. R9-22-202, 203, 28-201, 42
CFR 438.208, AHCCCS Medical Policy Manual Chapter 300 Policy 310-DD

PURPOSE

This policy outlines the coverage for transplants, related services, and immunosuppressant medications.

DEFINITIONS

1. "Behavioral Health Professional" or BHP" means
 - a. An individual licensed under A.R.S. Title 32, Chapter 33, whose scope of practice allows the individual to:
 - i. Independently engage in the practice of behavioral health as defined in A.R.S. §32-3251, or
 - ii. 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,
 - b. A psychiatrist as defined in A.R.S. §36-501,

- c. A psychologist as defined in A.R.S. §32-2061,
 - d. A physician,
 - e. A behavior analyst as defined in A.R.S. §32-2091,
 - f. A registered nurse practitioner licensed as an adult psychiatric and mental health nurse, or
 - g. A registered nurse with:
 - i. A psychiatric-mental health nursing certification, or
 - ii. One year of experience providing behavioral health services
2. “Disability” means a physical or mental impairment that substantially limits one or more major life activities, a person who has a history or record of such an impairment, or a person who is perceived by others as having such an impairment.
3. “Early and Periodic Screening, Diagnostic, and Treatment” or EPSDT” is a comprehensive child health program of prevention, treatment, correction, and improvement of physical and behavioral health conditions for members under the age of 21, to ensure the availability and accessibility of health care resources as well as to assist Medicaid recipients in effectively utilizing

these resources. EPSDT services provide comprehensive health care through primary prevention, early intervention, diagnosis, medically necessary treatment, and follow-up care of physical and behavioral health conditions for AHCCCS Members less than 21 years of age. EPSDT services include screening services, vision services, dental services, hearing services and all other medically necessary mandatory and optional services as specified in Federal Law 42 U.S.C. 1396d(a) to correct or ameliorate defects and physical and behavioral health illnesses and conditions identified in an EPSDT screening whether or not the services are covered under the AHCCCS State Plan.

Limitations and exclusions, other than the requirement for medical necessity and cost effectiveness, do not apply to EPSDT services.

4. "Foundation for the Accreditation of Cellular Therapy" or FACT" is 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.

5. "Member" means the same as "Client" as defined in A.R.S. § 36-551.
6. "Organ Procurement and Transplantation Network" or "OPTN" is a public-private partnership operated through the United States Department of Health and Human Services and established through the National Organ Transplant Act (NOTA). The OPTN policies govern operation of all Member transplant hospitals, Organ Procurement Organizations (OPOs) and histocompatibility labs in the United States.
7. "Standard of Care" means 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.
8. "Second Level Review" means a review performed by a Division of Developmental Disabilities (Division) Medical Director who has the appropriate clinical expertise in managing a Member's condition or disease. Second Level Review is used to screen for

medical necessity and compare the findings to clinical data in the Member's medical record to ensure Division Members are receiving medically appropriate and high quality care.

9. "United Network for Organ Sharing" or UNOS" means a Private, non-profit organization that manages the nations' organ transplant system under contract with Organ Procurement and Transplantation Network , including managing the national transplant Waiting List and maintaining the database that contains all organ transplant data for every transplant event that occurs in the United States.
10. "Waiting List" as defined by OPTN, is a computerized list of candidates who are waiting to be matched with specific deceased donor organs for transplant.

POLICY

A. GENERAL INFORMATION

1. The Division of Developmental Disabilities (Division) shall follow all Federal, State and Arizona Health Care Cost Containment System (AHCCCS) requirements for coverage of transplants, related services, and immunosuppressant medications.

2. The Division shall delegate the responsibility of implementing this policy to the Administrative Services Subcontractors (AdSS) for Members enrolled in a subcontracted health plan.
3. The Division shall coordinate physical and behavioral health services for Members enrolled in the Tribal Health Program (THP), while the provision and administration of organ transplant benefits will be completed by AHCCCS Department of Fee for Service Management (DFSM).

B. COVERED TRANSPLANTS

1. The Division shall cover the following transplant types for Members aged 21 and older:
 - a. Heart;
 - b. Single lung and double lung ;
 - c. Heart-Lung;
 - d. Liver
 - e. Cadaveric kidney and living donor kidney;
 - f. Simultaneous liver and kidney;
 - g. Simultaneous pancreas and kidney;
 - h. Pancreas after kidney; and

- i. Hematopoietic Stem Cell Transplants:
 - i. Allogeneic related,
 - ii. Allogeneic unrelated,
 - iii. Autologous, and
 - iv. Tandem Hematopoietic Stem Cell Transplant.
2. The Division shall cover all non-experimental transplants for Members under the age of 21 under the Early and Periodic Screening Diagnostic and Treatment (EPSDT) Program that are medically 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 AMPM 310-DD.
3. The Division shall ensure that transplants are medically necessary, non-experimental, and federally reimbursable, state reimbursable, and fall within the medical Standard of Care for coverage.
4. The Division shall use national standards for transplantation which include policy for:

- a. Organ Procurement Transplant Network,
 - b. Centers for Medicare and Medicaid Services (CMS),
 - c. United Network for Organ Sharing, and
 - d. Foundation for the Accreditation of Cellular Therapy.
5. The Division shall cover Circulatory Assist Devices (CADs), including Left Ventricular Assist Devices (LVADs) services for destination therapy and as a bridge to transplant when medically necessary and non-experimental.
6. The Division shall cover corneal transplants and bone grafts when medically necessary, cost effective and non-experimental as specified in AMPM Exhibit 300-1 and AMPM Policy 820.
7. The Division Medical Director shall:
- a. Complete a Second Level Review of all denials for transplant services and transplant related immunosuppressant medications for Members,
 - b. Have the final authority to approve or deny transplant services, and
 - c. Consult with the AHCCCS Medical Director for THP or the assigned subcontracted health plan's Medical Director

when there are questions regarding the transplant services.

C. COVERED TRANSPLANT SERVICES

1. The Division shall cover the following services, as required by the specific type of transplant:
 - a. Inpatient or outpatient pre-transplant evaluation , which includes, but is not limited to, the following:
 - i. Physical examination,
 - ii. Psychological evaluation,
 - iii. Laboratory studies,
 - iv. Radiology and diagnostic imaging or procedures, and
 - v. Biopsies.
 - b. Donor search, Human Leukocyte Antigen (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. Inpatient or outpatient post-transplant care, which may include the following:
 - i. Laboratory studies,
 - ii. Radiology and diagnostic imaging or procedures,
 - iii. Biopsies,
 - iv. Home health,
 - v. Skilled nursing facility services,
 - vi. All related transplant medications, including transplant related immunosuppressant medications, as referenced in Division Medical Manual Policy 310-V, and
 - vii. Transportation, and room and board for the transplant candidate, donor and, if needed, one adult caregiver as identified by the transplant facility.
 - 1) Coverage is limited to medical treatment transportation, to and from the facility, during the time it is necessary for the Member to remain in close proximity to the transplant center.

- 2) Coverage includes the periods of evaluation, on-going testing, transplantation, and post-transplant care by the transplant center.
2. The Division shall ensure the Living Donor Coverage is limited to the following when provided in the United States:
 - a. Evaluation and testing for suitability;
 - b. Solid organ or hematopoietic stem cell procurement, processing, and storage; and
 - c. Transportation and lodging when it is necessary for:
 - i. The potential donor to travel for testing to determine if they are a match, and
 - ii. Donating either stem cells or organs.

D. CONDITIONS FOR TRANSPLANTATION

1. The Division through oversight of the AdSS shall ensure the following conditions are met for transplantation:
 - a. Transplant candidates meet the criteria to be added to the Waiting List.

- b. Medical comorbidities are assessed through history and physical with a plan developed for appropriate care and ensure the following:
 - i. Changes in medical conditions shall be assessed for the impact upon transplant candidacy.
 - ii. All transplant candidates shall undergo routine age-condition appropriate screening for disease.
- c. Identified indolent or chronic infections have a plan of containment in accordance with an infectious disease specialist's recommendation.
- d. Members with identified neoplasms are assessed in accordance with an oncologist's recommendations.
- e. Psychosocial environment is assessed, and appropriate plans are generated to mitigate issues of adherence.
- f. For Members with prior adherence issues, plans with a BHP are developed.
- g. The Division shall ensure that Members with substance use disorder(s) have:

- i. Plans for treatment before and after the organ replacement; and
- ii. Consultation with a BHP who will work as a part of the treatment team to support the Member needs and maintain wellness and recovery oriented treatment, services and supports.

E. TRANSPLANT SERVICES AND SETTINGS

1. The Division through oversight of the AdSS shall ensure solid organ transplant services are provided in a CMS certified and UNOS approved transplant center which meets the Medicare conditions for participation and special requirements for transplant centers as specified in 42 CFR Part 482.
2. The Division through oversight of the AdSS shall ensure hematopoietic stem cell transplant services are provided in a facility that has achieved FACT accreditation. The facility shall meet the Medicare conditions for participation and any additional federal requirement for transplant facilities.

3. The Division through oversight of the AdSS shall ensure reimbursement is only available for transplant centers that meet the above requirements.

F. ADDITIONAL REQUIREMENTS

1. The Division shall ensure the AdSS covers out-of-network solid organ or hematopoietic stem cell transplants that meet the following requirements:
 - a. Services are covered for Members who have current medical requirements that cannot be met by an AHCCCS contracted transplant center.
 - b. Medical requirements for an out-of-network transplant request are clearly documented, specifying the level of technical expertise or program coverage that is not provided at an AHCCCS contracted facility.
 - c. Review the quality and outcome data published for the out-of-network facility.
 - d. The Division shall ensure the AdSS cover solid organ living donor-related costs for pediatric kidney and liver transplants and adult kidney transplants.

2. The Division shall consider living donor transplants on a case-by-case basis for solid organs other than pediatric and adult kidney and pediatric liver when medically necessary and cost effective.
 - a. Payment is limited for solid organ living donors other than pediatric and adult kidney and pediatric liver to the surgical procedure and follow-up post-op care provided to the donor through post-op day three.
 - b. For any additional charges, the living donor shall accept the terms of financial responsibility for the charges associated with the transplant that are in excess of the AHCCCS Specialty Contract for Transplantation Services.
3. The Division shall provide limited coverage for medically necessary and non-experimental services following the discharge from the acute care hospital, if a Division Member receives a transplant that is not covered by AHCCCS guidelines.
 - a. Excluded services:
 - i. Evaluations and treatments to prepare for transplant candidacy,

- ii. The actual transplant procedure and accompanying hospitalization, or
 - iii. Organ or tissue procurement.
 - b. Covered services include:
 - i. Transitional living arrangements appropriately ordered for post-transplant care when the Member does not live in close proximity to the transplant center,
 - ii. Essential laboratory and radiology procedures,
 - iii. Therapies that are medically necessary post-transplant,
 - iv. Immunosuppressant medications, and
 - v. Transportation that is medically necessary post-transplant.
- 4. The Division shall utilize the AHCCCS Specialty Contract for Transplantation Services for second covered organ transplant performed during the follow-up care periods of the first transplant.

5. The Division shall utilize the AHCCCS Reinsurance Processing Manual for transplantation reinsurance standards.
6. The Division shall utilize the AHCCCS Specialty Contract for Transplantation Services for detailed information regarding transplant coverage and payment for transplant services and transplant related services.

G. TRANSPLANT CARE COORDINATION

1. The Division's Transplant Coordinator shall coordinate with the AdSS Transplant Coordinator or the AHCCCS Transplant Coordinator at least quarterly and on an ad hoc basis to ensure Member's health services needs are being met and to ensure continuity of care.
2. The Division shall ensure on a quarterly basis, the subcontracted health plans submit Division specific AHCCCS Transplant Logs for review and tracking.
3. The Division shall ensure Members receiving care through the Tribal Health Program who are being considered for transplant services, will coordinate with the Transplant Coordinator to ensure continuity of care for the Member is maintained.

4. The Division Transplant Coordinator shall notify the Division Support Coordinator regarding the Member's transplant status. The Division Support Coordinator will work with the planning team, the Division Transplant Coordinator, and other adjunct services or support representatives and the Member to identify and address needs, modify the planning document to support the delivery of services and support as needed.

H. ORGAN TRANSPLANT ELIGIBILITY

1. The Division shall not, solely on the basis of a Member's Disability, do any of the following:
 - a. Determine that the Member is ineligible to receive an organ transplant
 - b. Deny the Member's medical or other services related to an organ transplant, including:
 - i. Evaluation,
 - ii. Surgery,
 - iii. Counseling, and
 - iv. Postoperative treatment.

- c. Refuse to refer the Member to a transplant hospital or other related specialist for evaluation or receipt of an organ transplant.
 - d. Refuse to place the individual on an organ transplant Waiting List or place the Member at a position lower in priority on the list than the position the Member would be placed if not for the Member's Disability.
 - e. Decline insurance coverage for the Member for any procedure associated with the receipt of an organ transplant or related services associated with the receipt of an organ transplant or for related services if the procedure or services would be covered under such insurance for the Member if not for the Member's Disability.
2. The Division shall not consider a Member's inability to independently comply with posttransplant medical requirements as medically significant if the Member has a known Disability and the necessary support system to assist the Member in reasonably complying with the requirements.

I. DIVISION OVERSIGHT

1. The Division shall oversee the AdSS utilizing the following methods to ensure compliance with policy:
 - a. Annual Operational Review of each AdSS,
 - b. Review and analyze deliverable reports submitted by the AdSS, and
 - c. Conduct oversight meetings with the AdSS for the purpose of:
 - i. Reviewing compliance,
 - ii. Addressing concerns with access to care or other quality of care concerns,
 - iii. Discussing systemic issues, and
 - iv. Providing direction or support to the AdSS as necessary.

Signature of Chief Medical Officer: 
[Anthony Dekker \(Apr 24, 2023 10:21 PDT\)](#)
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