320-B MEMBER PARTICIPATION IN EXPERIMENTAL SERVICES AND CLINICAL TRIALS

EFFECTIVE DATE: March 1, 2023
REFERENCES: A.R.S. §36-1331; A.R.S. §36-1336; AMPM 320-B

PURPOSE

This policy describes the responsibilities related to Experimental Services and Qualifying Clinical Trials for Arizona Long Term Care System (ALTCS) eligible members.

DEFINITIONS

1. "Eligible Patient" means a patient who meets all of the following conditions:
    a. Has a life-threatening disease or condition or a severely debilitating illness, attested to by the patient's physician.
    b. Has considered all other treatment options currently approved by the United States Food and Drug Administration.
    c. Has received a recommendation from the patient's physician for an Individualized Investigational Treatment

based on an analysis of the patient's genomic sequence, human chromosomes, deoxyribonucleic acid, ribonucleic acid, genes, gene products, such as enzymes and other types of proteins, or metabolites.

d. Has given written informed consent for the use of the individualized investigational drug, biological product or device.

e. Has documentation from the patient's physician that the patient meets the requirements of this paragraph.

2. "Experimental Services" means a service which is not generally and widely accepted as a standard of care in the practice of medicine in the United States and is not a safe and effective treatment for the condition for which it is intended or used as specified in A.A.C. R9-22-203.

3. "Individualized Investigational Treatment" means

a. A drug, biological product or device that is unique to and produced exclusively for use by an individual patient based on the patient's own genetic profile.

b. Includes individualized gene therapy, antisense oligonucleotides and individualized neoantigen vaccines.

4. "Qualifying Clinical Trial" means any clinical phase of development that is conducted in relation to the prevention, detection, or treatment of any serious or life threatening disease or condition and is described in any of clauses (i)-(iii) of section 1905(gg)(2)(A) of the Act. A study or investigation must be approved, conducted, peer-reviewed, or supported (including by funding through in-kind contributions) by national organizations.

5. "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.

POLICY

A. PARTICIPATION IN CLINICAL TRIALS

1. The Division shall ensure that members may participate in clinical trials if they desire, but will not reimburse for the Experimental Service.
2. The Division shall cover services related to the Qualifying Clinical Trial, including but not limited to:
    a. Routine care,
    b. Screenings,
    c. Laboratory tests,
    d. Imaging services,
    e. Physician services,
    f. Treatment of complications arising from clinical trial participation, or
    g. Other medical services and costs.
3. The Division shall not block or attempt to block an Eligible Patient's access to an Individualized Investigational Treatment.
4. The Division Medical Director shall:

a. Complete a Second Level Review of all requests for participation in Experimental Services and/or clinical trials for members.

b. Have the final authority to approve or deny the member's participation in Experimental Services and/or clinical trials.

c. Consults with the assigned AHCCCS Medical Director for Tribal Health Plan (THP) or the assigned subcontracted health plan's Medical Director when there are questions regarding the member's participation in Experimental Services and/or clinical trials.

B. COVERAGE DETERMINATION

1. The Division shall ensure coverage for a member to participate in a Qualifying Clinical Trial. Coverage shall be:

   a. Expedited and completed within 72 hours regardless of the geographic location or if the provider is in network;

   b. Based on where the clinical trial is conducted, including out of state; or

c. Based on whether the provider treating the member is outside of the network, the member may not be denied.

2. The Division's Medical Director shall review a member's participation in an FDA Phase I or Phase II clinical trial for approval. Factors for consideration for approval will include:

a. The clinical regimen is well-designed, and adequate protection of the member's welfare is assured;

b. Provider specification of the clinical trial and any associated service are not provided to prevent, diagnose, monitor, or treat complications resulting from participation in the clinical trial;

c. Verification that full financial liability for the clinical trial is taken by the researcher or the sponsor, and not be charged to, or paid by AHCCCS;

d. The trial provides adequate participant information and assures participant consent;

e. Completion of Attachment A and Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial;

f. Fees, finder's fees, or other payment for referring members for clinical trials are not received; and

g. The member's primary care provider shall not have any financial interest in the clinical trial.

3. The Division shall ensure members rights are being protected when members are approved to participate in a clinical trial.

Signature of Chief Medical Officer: Anthony Dekker (Feb 21, 2023 12:22 MST)
Anthony Dekker, D.O.