320-B MEMBER PARTICIPATION IN EXPERIMENTAL SERVICES AND CLINICAL TRIALS

EFFECTIVE DATE: May 17, 2023
REFERENCES: AMPM 320-B

PURPOSE

This policy describes the responsibilities related to Experimental Services and Qualifying Clinical Trials. It applies to the Division of Developmental Disabilities' Administrative Services Subcontractors (AdSS).

DEFINITIONS

1. "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.
2. "Member" means the same as "Client" as defined in A.R.S. § 36-551.
3. "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 nationally recognized medical research organizations or institutions.

4. "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 AdSS shall ensure that Members may participate in clinical trials, but shall not reimburse for the Experimental Services.

2. The AdSS 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 AdSS shall not block or attempt to block an Eligible Patient's access to an Individualized Investigational Treatment.

B. COVERAGE DETERMINATION

1. The AdSS shall expedite and complete a determination of coverage for a Member to participate in a Qualifying Clinical Trial within 72 hours regardless of the geographic location or if the provider is in network.

2. The AdSS shall not deny coverage of a routine member's costs based on:
    a. Where the clinical trial is conducted, including out of state; or
    b. Whether the provider treating the Member is outside of the network.
3. The AdSS Chief Medical Officer, Medical Director, or designee shall describes the responsibilities related to Experimental Services and Qualifying Clinical Trials. It applies to the Division of Developmental Disabilities' Administrative Services Subcontractors (AdSS).using the following criteria:
    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 has no financial interest in the clinical trial.

4. The AdSS shall submit a Second Level Review to the Division for any Member to participate in Experimental Services or Qualifying Clinical Trial prior to approving or denying services.

5. The AdSS shall ensure Members rights are being protected when approved to participate in a clinical trial.

Signature of Chief Medical Officer: Anthony Dekker (May 10, 2023 11:12 PDT)
Anthony Dekker, D.O.