

320-B - MEMBER PARTICIPATION IN EXPERIMENTAL SERVICES AND CLINICAL TRIALS

EFFECTIVE DATES: 10/01/94, 10/01/18, 10/01/22

APPROVAL DATES: 10/01/01, 07/01/04, 06/01/07, 03/01/09, 07/01/12, 09/20/18, 06/07/22

I. PURPOSE

This Policy applies to ACC, ACC-RBHA, ALTCS E/PD, DCS/CHP (CHP), and DES/DDD (DDD) Contractors; Fee-For-Service (FFS) Programs including: the American Indian Health Program (AIHP), Tribal ALTCS, TRBHA; and all FFS populations, excluding Federal Emergency Services (FES). (For FES, refer to AMPM Chapter 1100). AHCCCS does not cover Experimental Services; however, this Policy establishes Contractor and FFS Program responsibilities related to Qualifying Clinical Trials.

II. DEFINITIONS

For purposes of this Policy:

QUALIFYING CLINICAL TRIAL 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.

Additional Definitions are located on the AHCCCS website at: [AHCCCS Contract and Policy Dictionary](#).

III. POLICY

Members who are enrolled with a Contractor or who are receiving services on an FFS basis may participate in clinical trials; however, AHCCCS will not reimburse the experimental service as per A.A.C. R9-22-203.

AHCCCS will cover services related to the qualifying clinical trial including but not limited to: routine care, screenings, laboratory tests, imaging services, inpatient services, physician services, treatment of complications arising from clinical trial participation, or other medical services and costs, consistent with AHCCCS Policy and Arizona Administrative Code . Costs for services that are solely for the purpose of clinical data will not covered.

Participation in the clinical trial will not result in the loss of the member's other AHCCCS benefits.

COVERAGE DETERMINATION REQUIREMENTS

A determination with respect to coverage under section 1905(a)(30) of the Social Security Act for a member to participate in a qualifying clinical trial must be expedited and completed within 72 hours regardless of the geographic location or if the provider is in network. Coverage of routine member costs based on where the clinical trial is conducted, including out of state, or based on whether the provider treating the member is outside of the network may not be denied.

Member or FFS member participation in an FDA Phase I or Phase II clinical trial shall be approved by the member's Contractor or by the AHCCCS Chief Medical Officer or designee. If a Contractor approves participation of one or more members in a clinical trial, the Contractor shall ensure that the member's rights are protected. The basis for consideration will include:

1. Provider specification of the clinical trial and any associated service that is not provided to prevent, diagnose, monitor, or treat complications resulting from participation in the clinical trial, and verification that full financial liability for the clinical trial is taken by the researcher or the sponsor, and these services will not be charged to, or paid by, AHCCCS.
2. The clinical trial regimen is well-designed, and adequate protection of the member's welfare is assured. The trial provides adequate participant information and assures participant consent.
3. The Contractor shall ensure completion of Attachment A, Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial.
4. Contractor employees and/or providers cannot receive fees, finder's fees, or other payment for referring members for clinical trials. The member's primary care provider shall not have any financial interest in the clinical trial and cannot accept a finder's fee for referral of a member to participate in the clinical trial