TITLE Request for New Technology, Experimental or Investigational Therapies, and Clinical Trials	POLICY NUMBER HS-MM-07
RESPONSIBLE AREA Health Coordination	EFFECTIVE DATE 08/31/2023
Initiated: 06/13/02 **CHP Policy Committee Approval**: 06/01/04, 01/15/05, 02/09/06, 04/11/07, 08/05/08, 09/23/09, 10/05/10, 10/21/11, 10/17/12, 09/16/13; 11/17/14; 12/04/15; 11/03/16; 09/21/17; 12/14/18; 11/26/19; 09/14/20; 08/15/21; 08/15/22; 08/15/23	

STATEMENT/PURPOSE

This policy sets forth the guidelines used for determination of coverage of a new technology, experimental or investigation therapies.

AUTHORITY

A.R.S. § 8-512. Comprehensive medical and dental care; guidelines.

45 CFR 46.101; 45 CFR 46.409; and 21 CFR 50.56. Protection of Human Subjects.

A.A.C. R9-22-201. Scope of Services.

A.A.C. R9-22-203. Experimental Services.

The Intergovernmental Agreement (IGA) between the Arizona Health Care Cost Containment System (AHCCCS) and the Department of Child Safety (DCS) for DCS CHP outlines the contractual requirements for compliance with continuity and quality of care coordination for all members.

The contract between the Department of Child Safety (DCS) for the Comprehensive Health Plan (CHP) and its Managed Care Organization (MCO) contractor outlines the contractual requirements for compliance with the request for new Technology, Experimental or Investigational Therapies and Clinical Trials.

DEFINITIONS

Experimental Services: 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.

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.

New Technologies: for the purpose of this policy includes new technologies, or new uses of existing technology and experimental or investigational procedures. This includes medical, behavioral health, dental procedures and therapies, pharmaceuticals and devices.

POLICY

Coverage decisions of new technologies are addressed on an as needed basis. Children in foster care are considered a vulnerable population, and any experimental or untested therapies are considered with great scrutiny, and with the consent and involvement of the custodial guardian, the court system and the biologic parents when applicable.

DCS CHP requires Prior Authorization (PA) for any requests for new technology, new uses of existing technology, experimental or investigational procedures, or participation in qualifying clinical trials. PA decisions are based upon the medical necessity of the proposed therapy, availability of alternate effective treatment, including cost effectiveness and potential patient outcome. PA determinations comply with Arizona Health Care Cost Containment System (AHCCCS) guidelines on experimental services.

All requests for experimental therapies are reviewed with the DCS CHP CMO.

DCS CHP complies with the Department of Child Safety (DCS) Program Policy, Chapter 3, Section 7.1, Medical Services for Children in Out of Home Care, for member participation in clinical trials, including appropriate consents, authorizations from DCS supervisors, appointment of an independent advocate for the child, and relevant court approvals.

Experimental Therapy coverage decisions utilize consideration of national Medicare coverage decisions, and coverage decisions made by Medicare intermediaries and other Medicare carriers in addition to national Medicare coverage decisions, and Federal and State Medicaid coverage decisions, any published or unpublished information sources that establish that a new medical service or technology represents an advance which substantially improves diagnosis or treatment, and any endorsements by national medical bodies or panels regarding scientific efficacy and rationale as available.

DCS CHP entrusts its contracted MCO with the evaluation of the requested new technology or experimental services. The contracted MCO maintains a robust evaluation process that is outlined in policy 7000.20D Technology Assessment.

Experimental services are not reimbursable by AHCCCS per A.A.C. R9-22-203 and are not covered by DCS CHP.
If a child in out-of-home care is authorized to participate in a qualifying clinical trial, DCS CHP covers 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 trial data are not be covered.

Determination with respect to coverage for a member to participate in a qualifying clinical trial is expedited and completed within 72 hours regardless of the geographic location or if the provider is in network, under section 1905(a)(30) of the Social Security Act. 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.

If a member is authorized to participate in FDA Phase I or Phase II clinical trials, DCS CHP provides notification to AHCCCS DHCM, Medical Management Unit, which includes assurance that the member's rights are protected. This includes:

- 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 of full financial liability for the clinical trial are taken by the researcher or the sponsor and these services are not charged to, or paid by AHCCCS.
- The clinical trial regimen is well designed and has assured that there is adequate protection of the participant's welfare. The trial provides adequate information to the participant and assures participant consent.
- Neither the health plan, contracted MCO, or provider or their employees can receive fees, finder's fees or other payment for referring the members for experimental service. This includes the primary care provider, who cannot have any financial interest in the experimental service and cannot accept finder's fees for referral of the member to participate in the experimental service.

PROCEDURE

Requests for coverage of experimental therapies, new technologies, or new uses of existing technology, experimental or investigational procedures, or participation in clinical trials are submitted as Prior Authorization (PA) requests *(See DCS CHP Policy HS-MM-04, Prior Authorization)*.

All PA requests for new technologies submitted to DCS CHP's Health Services Unit for evaluation are reviewed by the Chief Medical Officer (CMO).

PA determinations for requests for clinical services are processed within the appropriate PA timelines*(See DCS CHP Policy HS-MM-04, Prior Authorization)*. Urgent requests are made as expeditiously as the member's condition warrants, but no later than 72 hours from receipt of the request.

When evaluating PA requests for new technologies, DCS CHP considers state and federal statutes and resources, AHCCCS and Centers for Medicare and Medicaid Services (CMS) guidance, national Medicare and Medicaid carrier coverage decisions, medical necessity, cost effectiveness, potential patient outcomes and side-effects. DCS CHP also considers locally and nationally recognized subject matter experts, any published or unpublished information sources that establish that a new medical service or

technology represents an advance which substantially improves diagnosis or treatment, any national Medicare or Medicaid coverage decisions, and any endorsements by national medical bodies or panels regarding scientific efficacy and rationale.

DCS CHP verifies that appropriate consents are obtained on behalf of the member prior to issuing authorization determinations on new technologies.

Authorization determinations and rationale are discussed at quarterly Medical Management (MM) Committee meetings and documented in the meeting minutes.

DCS CHP trends requests for new technologies and evaluates the prevailing rationale for new technologies. Trends are identified as part of Utilization Process Review are researched and reviewed. Trends are then discussed in MM committee meetings. If trends are identified that support a coverage decision, practice guidelines are developed.

Any changes in DCS CHP coverage decisions of new therapies are discussed at MM committee meetings along with the rationale and literature supporting the decisions and documented in the minutes.

REFERENCES

AHCCCS Medical Policy Manual (AMPM) Chapter 300, Policy 320-B, Member Participation in Experimental Services

AHCCCS Medical Policy Manual (AMPM) Chapter 1000, Policy 1020, Medical Management Scope and Components

DCS Program Policy Chapter 3, Section 7.1, Medical Services for Children in Out of Home Care

AHCCCS Contract and Policy Dictionary

RELATED FORMS

N/A