

**MEDICAID SERVICES MANUAL  
TRANSMITTAL LETTER**

October 25, 2022

**TO:** CUSTODIANS OF MEDICAID SERVICES MANUAL

**FROM:** CASEY ANGRES  
MANAGER OF DIVISION COMPLIANCE

**SUBJECT:** MEDICAID SERVICES MANUAL CHANGES  
CHAPTER 1500 – HEALTHY KIDS PROGRAM

**BACKGROUND AND EXPLANATION**

Revisions to Medicaid Services Manual (MSM) Chapter 1500 – Healthy Kids Program are being proposed to remove the policies related to Clinical Studies / Experimental Treatment as this policy will be updated and relocated to MSM 600 – Physician Services.

Entities Financially Affected: This proposed change affects all Medicaid enrolled providers delivering Healthy Kid Exams / annual wellness visits and sick visits. Those Provider Types (PTs) include but are not limited to: Outpatient (PT 12), Behavioral Health Outpatient Treatment (PT 14), Physicians/Osteopath (PT 20), Advanced Practice Registered Nurse (PT 24), School Health Services (PT 60), Nurse Midwives (PT 74), and Physician’s Assistant (PT 77).

Financial Impact on Local Government: No impact on local government known.

These changes are effective: October 26, 2022.

<b>MATERIAL TRANSMITTED</b>	<b>MATERIAL SUPERSEDED</b>
MTL OL MSM Chapter 1500 - Healthy Kids Program	MTL NA MSM Chapter 1500 - Healthy Kids Program

<b>Manual Section</b>	<b>Section Title</b>	<b>Background and Explanation of Policy Changes, Clarifications and Updates</b>
<b>Attachment A Policy #15-1</b>	<b>Clinical Studies</b>	Deleted the Clinical Studies Policy under this attachment as it will be relocated to MSM 600, Attachment A, #6-01, Qualifying Clinical Trials.
<b>Attachment A Policy #15-2</b>	<b>Experimental Treatment</b>	Deleted the Experimental Treatment Policy under this attachment as it will be relocated to MSM 600, Attachment A, #6-01, Qualifying Clinical Trials.

POLICY #15-1	CLINICAL STUDIES	EFFECTIVE DATE: NOVEMBER 1, 2014
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For policy related to clinical studies, please refer to MSM 600 – Physician Services, Attachment A, Policy #6-01, Qualifying Clinical Trials (QCT).

**DESCRIPTION**

~~Nevada Medicaid covers the routine costs of qualifying phase III and IV clinical trials for children less than 21 years of age. Reasonable and necessary items and services used to diagnose and treat complications arising from participation in phase III and IV clinical trials are covered. These services must be a Nevada Medicaid covered service.~~

**POLICY**

~~Any clinical trial receiving Medicaid coverage of routine costs must meet the following requirements:~~

- ~~1. The subject or purpose of the trial must be the evaluation of an item or service that is covered by Nevada Medicaid (e.g., physicians' service, Durable Medical Equipment (DME), diagnostic test) and is not excluded from coverage (e.g., cosmetic surgery);~~
- ~~2. The trial must not be designed exclusively to test toxicity or disease pathophysiology, it must have therapeutic intent;~~
- ~~3. Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers; and~~
- ~~4. The clinical trial is approved by one of the following:
 
  - ~~a. National Institute of Health (NIH);~~
  - ~~b. Department of Defense (DOD);~~
  - ~~c. Veterans Affairs (VA);~~
  - ~~d. Centers for Disease Control (CDC);~~
  - ~~e. Centers for Medicare & Medicaid Services (CMS);~~
  - ~~f. Agency for Healthcare Research & Quality (AHRQ); or~~
  - ~~g. National Cancer Institute (NCI).~~~~

**PRIOR AUTHORIZATION IS REQUIRED**

~~Clinical trials that meet the qualifying coverage criteria will receive Medicaid coverage of routine costs after prior authorization from the Quality Improvement Organization (QIO) like vendor.~~

POLICY #15-1	CLINICAL STUDIES	EFFECTIVE DATE: NOVEMBER 1, 2014
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~~COVERAGE AND LIMITATIONS~~~~Covered Services~~

- ~~1. Items or services that are typically provided absent a clinical trial (e.g., conventional care);~~
- ~~2. Items or services required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service or the prevention of complications; and~~
- ~~3. Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications.~~

~~Non-Covered Services~~

- ~~1. Phase I or II clinical trials.~~
- ~~2. Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly Computed Tomography (CT) scans for a condition usually requiring only a single scan).~~
- ~~3. Items and services customarily provided by the research sponsors free of charge for the enrollee in the trial.~~
- ~~4. For items and services, including items and services for which Medicaid reimbursement is not available, Medicaid only covers the treatment of complications arising from the delivery of the non-covered item or service and unrelated reasonable and necessary care. However, if the item or service is not covered by Medicaid and is the focus of a qualifying clinical trial, the routine costs of the clinical trial (as defined above) will be covered by Medicaid but the non-covered item or service, itself, will not.~~

~~NOTE: For policy regarding pharmaceutical clinical studies, please refer to MSM Chapter 1200, Prescribed Drugs.~~

POLICY #15-2	EXPERIMENTAL TREATMENT	EFFECTIVE DATE: NOVEMBER 1, 2014
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For policy related to experimental treatment, please refer to MSM 600 – Physician Services, Attachment A, Policy #6-01, Qualifying Clinical Trials (QCT).

~~DESCRIPTION/POLICY~~

~~Nevada Medicaid does not cover any item or service that is not medically necessary, that is unsafe or is not generally recognized as an accepted method of medical practice or treatment.~~

~~PRIOR AUTHORIZATION IS REQUIRED~~

~~If experimental treatment is medically necessary, providers must request prior authorization for services which may fall into the above category prior to rendering service.~~

~~COVERAGE AND LIMITATIONS~~

~~Nevada Medicaid completes prior authorization on medical services to assure that the care and the services proposed are actually needed, are equally effective, less expensive alternatives have been given consideration and the proposed service and materials conform to commonly accepted standards.~~

~~Nevada Medicaid's QIO-like vendor completes the authorization review.~~