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Section 210: Coverage of the Routine Costs of Care Associated with Clinical Trials

On December 21, 2020, the President of the United States signed into law the Consolidated Appropriations Act, 2021 (CAA, 2021). Section 210 of the CAA, 2021, mandates Medicaid coverage of the routine costs of care associated with clinical trials beginning on January 1, 2022. As a result, all states and territories will be required to cover and reimburse for the routine costs of care for services associated with Medicaid enrollees' participation in a qualifying clinical trial.

The State Medicaid agency seeks to implement the policies and procedures described below, which are different than the policies and procedures otherwise applied under the Medicaid state plan.

Medicaid regulations require managed care organizations to follow Medicaid coverage and reimbursement policies. This State Plan Amendment applies to both managed care and fee-for-service Medicaid plans and those enrolled in such plans.

Please check the space following each number to comply with the implementation requirements set forth below.

Section A – Definitions

Qualifying Clinical Trial

The phrase "qualifying clinical trial" shall refer to a trial for devices, biologics, imaging, radiation therapy, surgeries or other modalities, behavior change, drugs, procedures, items, or services. The "qualifying clinical trial" may be a phase 0, I, II, III, or IV clinical trial (i.e., any clinical phase of development) that is conducted in relation to the prevention, detection, treatment, management of symptoms, or quality-of-life associated with any serious or life-threatening disease or condition (including cancer). One or more of the following conditions apply:

1. The State Medicaid Program makes a determination that the study or investigation is a qualifying clinical trial;
2. The study or investigation is conducted under an investigational new drug application or an investigational device exemption reviewed by the federal Food & Drug Administration;
3. The study or investigation is a drug trial that is exempt from having an investigational new drug application or an investigational device exemption from the federal Food & Drug Administration; or
4. The study or investigation is approved or funded by
    a. The National Institutes of Health;
    b. The Centers for Disease Control and Prevention;
    c. The Agency for Health Care Research and Quality;
    d. The federal Centers for Medicare & Medicaid Services;

e. A cooperative group or center of any of the entities described in (a)-(d) or the federal Department of Defense or the federal Department of Veteran's Affairs;
f. A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants; or
g. The federal Department of Veterans Affairs, the federal Department of Defense, or the federal Department of Energy, provided that review and approval of the study or investigation occurs through a system of peer review that is comparable to the peer review of studies performed by the National Institutes of Health, including an unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

Serious or Life-Threatening Disease or Condition

Serious or life-threatening diseases or conditions include:

1. A disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.
2. A disease or condition with a potentially fatal outcome where the intent of the clinical trial is survival.
3. Serious diseases or conditions (also referred to as "severely debilitating") that cause major irreversible morbidity.

Qualified Individual

The phrase "qualified individual" shall refer to any individual enrolled in the State Medicaid Program, in any (mandatory and optional) Medicaid eligibility category, who a treating physician and the principal investigator of the trial determine meets the selection criteria of the qualifying clinical trial.

Coverage for the Routine Costs of Qualifying Clinical Trials

The State Medicaid Program shall cover and reimburse for the routine costs of care associated with participation in a qualifying clinical trial in addition to the standard care for a qualified individual.

Standard Care

Standard care includes items and services that are commonly used to prevent, diagnosis, monitor, or treatment of patients with similar diseases and conditions as the qualifying clinical trial. Patients enrolled in a qualifying clinical trial will continue to receive standard care concurrent with investigational items or services.

Routine Costs

Routine Costs **includes** any item or service provided to the individual under the qualifying clinical trial, including –

1. Any item or service provided to prevent, diagnose, monitor, or treat complications resulting from such participation, to the extent that the provision of such an item or service to the individual outside the course of such participation would otherwise be covered under the State plan or waiver; and
2. Any item or service required solely for the provision of the investigational item or service that is the subject of such trial, including the administration of such investigational item or service.
3. Items or services that are typically provided absent a clinical trial (e.g., standard care);
4. 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.

The following shall **not be included** within the routine costs:

1. The investigational item, device, or service itself that is the subject of the clinical trial; or
2. An item or service not otherwise covered as a Medicaid benefit outside of the clinical trial under the state plan or waiver; or
3. Items and services that are provided solely to satisfy the data collection and analysis needs of the clinical trial that are not used in the direct clinical management of the patient.
4. Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial.

Section B – Coverage

Requirements for State Medicaid Coverage of Routine Costs

1._____Any qualifying clinical trial for which Medicaid will cover routine costs must meet the following three requirements:

- The subject or purpose of the trial must be the evaluation of a device, biologic, imaging, radiation therapy, surgery or other modality, behavior change, drug, procedure, item, or service that falls within any mandatory or optional Medicaid benefit category.
- The trial may be designed exclusively to test toxicity or disease pathophysiology (stage I trials), or it may have therapeutic intent (stage II, III, and IV).
- Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.

2._____State Medicaid plans will be required to cover the routine costs of qualifying clinical trials that have certified that they meet the qualifying criteria, or that the State Medicaid agency determines is a qualifying trial, unless the state's Chief Clinical Officer subsequently finds that a clinical trial does not meet the qualifying criteria or jeopardizes the safety or welfare of Medicaid enrollees.

Fraud and Abuse

3._____Should the state find that a trial's principal investigator misrepresented that the trial met the necessary qualifying criteria in order to gain Medicaid coverage of routine costs, Medicaid coverage of the routine costs would be denied.

4._____In the case of such a denial, the Medicaid beneficiaries enrolled in the trial would not be held liable (i.e., would be held harmless from collection) for the costs of care.

5._____In the case of such a denial, the billing providers offering routine costs associated with the clinical trial would not be held liable for the costs, unless found to be acting in concert with the principal investigator upon state completion of the fraud and abuse investigation.

6._____Should the principal investigator be found to have misrepresented the nature of the trial, the state will handle the investigations of fraud and abuse in the manner described below.

State plan to handle fraud and abuse:

Section C - Eligibility

State Medicaid plans will cover the routine costs of care associated with qualifying clinical trials for all state Medicaid enrollees, regardless of the eligibility category into which they fall.

1._____Medicaid plans will cover and reimburse all standard care and routine costs associated with a qualifying clinical trial for all covered Medicaid enrollees, including those in special enrollment groups with partial benefits, mandatory eligibility groups, and optional eligibility groups, as indicated in the State Plan or waiver.

2._____All fee-for-service and managed care Medicaid plans will immediately cover standard care and the routine costs associated with a qualifying clinical trial for Medicaid enrollees the same day Medicaid coverage begins. No delay will occur between Medicaid enrollment and coverage of routine costs for a qualifying clinical trial.

3._____Although not mandatory, CMS encourages states that do not currently cover the two following eligibility groups to include them and indicate all routine costs and standard care will be covered under the Medicaid state plan: Certain Patients Needing Treatment for Breast or Cervical Cancer; and Presumptively Eligible Patients with Breast or Cervical Cancer.

4._____If a state agency chooses to cover additional eligibility groups not currently listed in the State Plan, states may do so by listing them in the chart below. Effective January 1, 2022, these enrollees will have the benefits as defined by the eligibility category into which they fall, as well as coverage of routine costs of care associated with participation in a clinical trial.

Additional List of eligibility groups with coverage of routine costs.

a._____

b._____

c._____

d._____

e._____

f._____

Section D – Benefits

Routine Costs Benefit

Coverage of routine patient costs by fee-for-service and managed care Medicaid plans performed in association with a qualifying clinical trial must include all items and services provided for the prevention, detection, or treatment of complications related to participation in the clinical trial in addition to the standard care the enrollee would receive if they were not enrolled in a trial.

1._____The state Medicaid plan will cover and reimburse all services falling under the following categories of services for Medicaid enrollees participating in a qualifying clinical trial.

2._____Coverage and reimbursement for the following services will occur regardless of enrollee participation in a qualifying trial. If the service is covered when a Medicaid beneficiary is not enrolled in a clinical trial, it will be covered regardless of clinical trial enrollment.

3._____No limitations will be set on the number of services an enrollee may receive in a given time period as standard care or as routine costs.

4._____The following categories of services, frequently provided in connection with a clinical trial, will be covered and reimbursed under the Medicaid plan and waivers. All items and services provided within these categories as detailed in the CPT book for the same year in which a Medicaid beneficiary is enrolled in a clinical trial will be covered and reimbursed by state Medicaid plans as indicated in the state's fee schedule.

Service	Mandatory	Optional
Office and Other Visits		
Office visits – new	X	
Office visits – established	X	
Hospital visit – initial	X	
Hospital visit – subsequent	X	
Hospital visit - critical care	X	
Emergency room visit	X	
Home visit	X	
Nursing home visit	X	

Consultations	X	
Physician Services		
Oncology - radiation therapy	X	
Oncology – other	X	
Drug Administration	X	
Imaging		
Standard imaging – chest	X	
Standard imaging – musculoskeletal	X	
Standard imaging – breast	X	
Standard imaging - contrast gastrointestinal	X	
Standard imaging - nuclear medicine	X	
Advanced imaging - CAT/CT/CTA: brain/head/neck	X	
Advanced imaging - MRI/MRA: brain/head/neck	X	
Echography/ultrasonography – eye	X	
Echography/ultrasonography - abdomen/pelvis	X	
Echography/ultrasonography – heart	X	
Echography/ultrasonography - carotid arteries	X	
Echography/ultrasonography - prostate, transrectal	X	
Imaging/procedure - heart including cardiac catheterization	X	
PET Scans		
Laboratory and Pathology Services		
Lab tests - routine venipuncture	X	
Lab tests - automated general profiles	X	
Lab tests – urinalysis	X	
Lab tests - blood counts	X	
Lab tests – glucose	X	
Lab tests - bacterial cultures	X	
Other tests – electrocardiograms	X	
Other tests - cardiovascular stress tests	X	
Other tests - EKG monitoring	X	
Supplies and Transportation		
Medical/surgical supplies – associated with routine costs	X	
DME needed for drug administration		
Drugs Administered through DME	X	
Transportation to clinical trial appointments		
Ambulance or transportation to medical care	X	
Prescription Drugs		
Supportive Care Drugs	X	
All other prescription drugs covered under Medicaid	X	
Inpatient Hospital Stays		
Other services the agency wishes to list – list below		

Drug Benefit:

6._____The agency makes the following adjustments to the day supply or quantity limit for covered outpatient drugs. The agency should only make this modification if its current state plan has limits on the amount of medication dispensed.

Please describe the increase in days or quantities that are allowed while the beneficiary is enrolled in a qualifying clinical and for which drugs.

7._____ A qualifying clinical trial may require the use of supportive care medications, covered as standard and/or routine costs, to prevent and manage adverse effects of the disease or condition, or its treatment. Supportive care medications shall not be restricted, subjected to clinical review, or limited on time or quantity so long as they are consistent with the qualifying clinical trial.

8._____For qualifying individuals enrolled in a qualifying clinical trial, the agency will make exceptions to their published Preferred Drug List if drug shortages occur or if a drug on the PDL is not available. This includes options for covering a brand name drug product that is a multi-source drug if a generic drug option is not available.

Transportation Benefit

9._____States must permit all Medicaid enrollees to use Medicaid's nonemergency medical transportation (NEMT) benefit to access all appointments associated with clinical trials in the same manner they are able to access the benefit for standard care.

10._____The agency will not impose any limitations on the NEMT benefit when used for enrollee participation in a qualifying clinical trial, including no restrictions on the number of rides, type of ride, and ride distance.

Network

11._____Qualifying individuals may receive routine costs associated with qualifying clinical trials from any Medicaid provider available to them, regardless of healthcare network.

12._____The network from which the qualifying individuals receive routine costs does not need to be from the same network in which the individual participates in the clinical trial.

Geography

13._____Medicaid will reimburse for routine costs and standard care for services furnished in another

state:

- if the qualifying clinical trial is not available for enrollment in the state in which the beneficiary resides; or
- If the qualified individual resides closer to a qualifying clinical trial site in another state.

14._____States will follow existing out-of-state payment policy for routine costs associated with qualifying clinical trials.

Site of Service

15._____The qualifying individual may receive routine costs at any Medicaid facility or non-facility setting at which the service may be provided.

Cost Sharing

16._____The agency suspends deductibles, copayments, coinsurance, and any other cost sharing charges for all routine care in association with participation in a qualifying clinical trial (i.e., any claim line with an X1 modifier).

Section E – Reimbursement for Routine Costs

Reimbursement

1._____Payment for the routine costs associated with clinical shall be equal to the reimbursement rates for services/items/procedures/devices not associated with a clinical trial as documented in the state Medicaid fee schedule.

2._____Payment for routine costs is based on the payment methodology applicable for the setting in which the service was furnished.

Coding and Billing

3._____Effective for claims with dates of service on or after January 1, 2022, it is mandatory to report a clinical trial number on claims for items/services provided in clinical trials/studies/registries, or under coverage with evidence development (CED). This is the number assigned by the National Library of Medicine (NLM) ClinicalTrials.gov Web site when a new study appears in the NLM Clinical Trials data base. This number is listed prominently on each specific study's page and is always preceded by the letters "NCT."

4._____Practitioners and institutional providers need to enter clinical trial and non-clinical trial services on separate line items when billing both types of services on the same claim.

5._____Items and services provided free-of-charge by research sponsors do not need to be reported to Medicaid. It is not necessary for a provider to show the items and services provided free-of-charge as part of clinical trial to receive payment for the covered routine costs (e.g., administration of a non-covered chemotherapeutic agent).

6._____Routine costs associated with a qualifying clinical trial will be billed on outpatient claims with the modifier X1[1] as defined below:

> X1 - Routine clinical service provided in an approved clinical research study for a qualifying individual enrolled in Medicaid
>
> Routine clinical services are defined as those items and services that are covered for Medicaid beneficiaries outside of the clinical research study; are used for the direct patient management within the study; and do not meet the definition of investigational clinical services. Routine clinical services may include items or services required solely for the provision of the investigational clinical services (e.g., administration of a chemotherapeutic agent); clinically appropriate monitoring, whether or not required by the investigational clinical service (e.g., blood tests to measure tumor markers); and items or services required for the prevention, diagnosis, or treatment of research related adverse events (e.g., blood levels of various parameters to measure kidney function).

7._____ICD-9 code: V70.7 or ICD-10 code: Z00.6 must be listed on the claim.

Section F – Communication

1._____The State Medicaid agency shall develop electronic and printed materials to inform beneficiaries in clear layman language informing enrollees of Medicaid coverage for the routine patient costs associated with clinical trials.

2._____The State Medicaid agency shall also develop electronic and printed materials to inform beneficiaries of the availability and no cost of patient navigator programs to negotiate the clinical trial participation process.

3._____These materials will be written at no greater than a 6th grade reading level, and the information will be made available to the public beginning on December 1, 2021 in the following locations:

Locations/websites where information will be made available to the public:

4._____The state will use existing patient navigator programs to help Medicaid enrollees gain entry to clinical trials and negotiate the clinical trial participation process.

[1] "XI" is a placeholder only

5._____If the state needs to expand the patient navigator program to meet demand, expansion must be addressed no later than January 1, 2022.