
SMD # 21-005

**RE: Mandatory Medicaid Coverage of
Routine Patient Costs Furnished in
Connection with Participation in
Qualifying Clinical Trials**

December 7, 2021

Dear State Medicaid Director:

The Center for Medicaid and CHIP Services (CMCS) is issuing this State Medicaid Director Letter outlining new Medicaid state plan requirements for assuring coverage of routine patient costs associated with participation in qualifying clinical trials. This guidance applies to states and territories and with respect to items and services furnished to Medicaid beneficiaries, including beneficiaries enrolled in Alternative Benefit Plans (ABPs), who are participating in a qualifying clinical trial on or after January 1, 2022.

Background

Historically, the Medicaid statute and its implementing regulations did not specify a clear requirement for coverage of routine costs associated with clinical trials, even if those routine costs were for items and services that ordinarily would be covered by a state's Medicaid program. Therefore, states (including the territories, unless otherwise noted) have had the flexibility to limit or exclude coverage for routine costs associated with clinical trials by defining medical necessity criteria, provider qualifications and limits on the amount, duration, and scope of services. Some states historically have determined that all services provided to a Medicaid beneficiary participating in a clinical trial were considered "experimental," and therefore not covered by Medicaid. On the other hand, we explained in guidance regarding dually eligible Medicare and Medicaid beneficiaries issued on October 30, 2000, that Medicaid may pay for otherwise covered services that are routine costs for clinical trials, provided all applicable requirements are met, including third party liability requirements.¹ To date, this State Medicaid Director Letter is the only guidance we have issued addressing Medicaid coverage of routine costs for clinical trials.

Mandatory Services

Division CC, Title II, Section 210 of the Consolidated Appropriations Act, 2021 (Public Law 116-260) (section 210) amended section 1905(a) of the Social Security Act (the Act), by adding to the definition of medical assistance a new benefit at section 1905(a)(30) for routine patient costs for items and services furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials, subject to further provisions in a new section 1905(gg). Section 210

¹ <https://www.medicaid.gov/Federal-Policy-Guidance/downloads/smd103000.pdf>

also amended sections 1902(a)(10)(A) and 1937(b)(5) of the Act to make coverage of this new benefit mandatory under the state plan and any benchmark or benchmark equivalent coverage also referred to as alternative benefit plans, or ABPs with respect to items and services furnished on or after January 1, 2022.

Pursuant to section 1905(a)(30) and 1905(gg)(1) of the Act, the routine patient costs that must be covered for a beneficiary participating in a qualifying clinical trial are any item or service provided to the individual under the qualifying clinical trial, including any item or service provided to prevent, diagnose, monitor, or treat complications resulting from participation in the qualifying clinical trial, to the extent that the provision of such items or services to the beneficiary would otherwise be covered outside the course of participation in the qualifying clinical trial under the state plan or waiver, including a demonstration project under section 1115 of the Act. Such routine services and costs also include any item or service required solely for the provision of the investigational item or service that is the subject of the qualifying clinical trial, including the administration of the investigational item or service. Some examples of routine costs in a clinical trial could include otherwise covered physician services or laboratory or medical imaging services that assist with prevention, diagnosis, monitoring or treatment of complications arising from clinical trial participation.

Items and Services Not Covered Under the New Mandatory Benefit

As described under section 1905(gg) of the Act, routine patient costs within the meaning of section 1905(a)(30) of the Act do not include any investigational item or service that is the subject of the qualifying clinical trial and is not otherwise covered outside of the clinical trial under the state plan, waiver, or demonstration project.

Similarly, routine patient cost does not include any item or service that is provided to the beneficiary solely to satisfy data collection and analysis for the qualifying clinical trial that is not used in the direct clinical management of the beneficiary and is not otherwise covered under the state plan, waiver, or demonstration project. For example, if a beneficiary has a condition that typically requires monitoring through an annual medical imaging scan and the beneficiary is participating in a clinical trial with a protocol that requires monthly medical imaging scans only to collect data on the effects of the investigational item or service, the additional monthly scans for purposes of clinical trial data collection would not be included in the beneficiary's routine patient costs to the extent they are not used for the direct clinical management of the beneficiary or are not otherwise covered under the state plan, waiver, or demonstration project.

Qualifying Clinical Trial

Section 1905(gg)(2) of the Act defines the term “qualifying clinical trial” for purposes of section 1905(a)(30) of the Act as a clinical trial in 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. Therefore, to meet the statutory definition, the “qualifying clinical trial” must also be one or more of the following:

- A study or investigation that is approved, conducted, or supported (including by funding through in-kind contributions) by one or more of the following:

- The National Institutes of Health (NIH);
- The Centers for Disease Control and Prevention (CDC);
- The Agency for Health Care Research and Quality (AHRQ);
- The Centers for Medicare & Medicaid Services (CMS);
- A cooperative group or center of any of the entities described above or the Department of Defense or the Department of Veterans Affairs;
- A qualified non-governmental research entity identified in the guidelines issued by the NIH for center support grants²;
- A clinical trial, approved or funded by any of the following entities, that has been reviewed and approved through a system of peer review that the Secretary determines comparable to the system of peer review of studies and investigations used by the NIH, and that assures unbiased review of the highest scientific standards by qualified individuals with no interest in the outcome of the review:
 - The Department of Energy
 - The Department of Veterans Affairs
 - The Department of Defense;
- A clinical trial that is one conducted pursuant to an investigational new drug exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act or an exemption for a biological product undergoing investigation under section 351(a)(3) of the Public Health Service Act; or
- A clinical trial that is a drug trial exempt from being required to have one of the exemptions in the prior bullet.

Coverage Determination Requirements

As provided in section 1905(gg)(3) of the Act, a determination with respect to coverage under section 1905(a)(30) of the Act for a beneficiary participating in a qualifying clinical trial must be expedited and completed within 72 hours and must be made without regard to the geographic location or network affiliation of the health care provider treating the beneficiary or the principal investigator of the qualifying clinical trial. This means that states must review and adjust, as necessary, any existing utilization management processes to ensure a coverage determination is completed within 72 hours. We interpret the geographic location or network affiliation requirement to mean that a state or territory may not deny coverage of routine patient costs based on where the clinical trial is conducted, including out of state, or based on whether the principal investigator or provider treating the beneficiary in connection with the clinical trial is outside of the network of the beneficiary's Medicaid managed care plan, if applicable. In the latter case, if a positive coverage determination is made, the state may either pay for the covered services on a fee-for-service basis as outside the scope of the managed care contract or require the managed care plan to cover the services out-of-network when the coverage requirement applies.

Coverage must also be based on an attestation regarding the appropriateness of the qualifying clinical trial by the health care provider and principal investigator and be made using a streamlined uniform form developed for state use by the Secretary, which is currently under

² While Section 210 of the Consolidated Appropriations Act references a qualified non-governmental research entity identified in the guidelines issued by the NIH for center support grants, NIH has clarified that no such guidelines exist.

development, and that will include the option to reference information regarding the qualifying clinical trial that is publicly available on a website maintained by the Secretary, such as clinicaltrials.gov. Further, coverage determinations must not require submission of the protocols of the qualifying clinical trial or any other documentation that may be proprietary or determined by the Secretary to be burdensome.

States that use a managed care delivery system must either cover the costs as required outside the scope of its managed care contracts or specify the applicable requirements in their managed care plan contracts and adjust capitation rates as appropriate for items and services furnished to Medicaid beneficiaries on or after January 1, 2022.

Exemption of Additional Expenditures from Payment Limits for Territories

Section 210 amended section 1108(g)(4) of the Act to include a new subparagraph (B), providing that expenditures for routine patient costs, as defined in section 1905(gg)(1), will not be taken into account in applying the allotment caps for the territories under 1108(f) of the Act. This provision is also effective for items and services furnished on or after January 1, 2022.

Exception for State Legislation

States that require legislative changes to implement coverage of routine patient costs as specified in section 1905(a)(30) of the Act will not be regarded as failing to comply with the requirements newly added by section 210, solely on the basis of their failure to meet these requirements before the first day of the first calendar quarter beginning after the close of the first regular session of the state legislature that begins after December 27, 2020, the date of enactment of the Consolidated Appropriations Act, 2021. For states that have a two-year legislative session, each year of the session is considered a separate regular session of the state legislature for purposes of this exception.

Essentially, this provision provides for an extension to the required start date of the new coverage requirement if the only reason the state cannot come into compliance by January 1, 2022 is due to lack of state legislation that is needed to meet the requirement. Not all states will be able to seek this extension, because it depends on the timing of the state's first regular legislative session that began after the date of enactment of the Consolidated Appropriations Act, 2021. If the Secretary determines that state legislation is needed to bring the state plan into compliance with the new coverage requirement, the Secretary will not consider the state to be out of compliance with the new coverage requirement solely on the basis of a failure to enact the required state legislation before the first day of the first calendar quarter beginning after the close of the first regular session of the state's legislature that begins after December 27, 2020. If a state's first regular legislative session beginning after December 27, 2020, was the calendar year that began on January 1, 2021, and ended on December 31, 2021, the state would not be able to seek this extension because it would have had only until December 31, 2021, to enact any required legislation, and the first day of the first calendar quarter that begins after that date is January 1, 2022 – the effective date for this provision.

If, however, a state's first regular legislative session beginning after December 27, 2020, does not end until on or after December 1, 2022, and the Secretary determines that legislation was necessary to meet the new coverage requirement, but the necessary legislative authorization was

not obtained, the state could seek to delay compliance with the new coverage requirement until the first day of the first calendar quarter after the legislative session ends. Such a state is expected to come into compliance with the new coverage requirement by the first day of the first calendar quarter after the end of the legislative session, unless the exception in section 1905(gg)(1) applies. If a state has a two-year legislative session, each year of the session shall be considered to be a separate regular session of the state legislature for purposes of this extension. This means that a state would not have a longer extension if it has a two-year legislative session; such a state is treated like a state with a one-year legislative session, and any applicable extension ends on the first day of the first calendar quarter following the end of the first year of the two-year session.

CMS will grant an extension based on legislative delay only if the timing of the state’s legislative session is the only reason that a state cannot meet the requirement, and only when the first regular legislative session that began after December 27, 2020, ends on or after December 1, 2022, as discussed above. States should submit requests for the legislative delay extension on or before January 1, 2022, to the Regional SPA/Waiver mailbox that is currently used for Medicaid SPA submissions. If the state is participating in the pilot for the new “One CMS Portal,” the request for the legislative delay extension should be submitted via the portal. The request should include documentation to support that the state’s first regular legislative session that began after December 27, 2020, did not end until on or after December 1, 2022, that state legislation is needed to come into compliance with the new coverage requirement, and that the legislative delay is the only reason the state cannot come into compliance as of December 1, 2022. States may, but are not required to, use the following format for their legislative delay extension submission:

_____ [Insert name of state] requests an exception based on the need for legislative authority to cover the benefit described in section 1905(a)(30) of the Social Security Act, and submits documentation to support that the state’s first regular legislative session that began after December 27, 2020, will not end until on or after December 1, 2022. [Describe the documentation that is attached or that accompanies the request and include information about the state’s legislative calendar so CMS can determine the state’s compliance date.]

States that are granted an extension due to legislative delay will still need to follow the state plan amendment (SPA) submission requirements below and submit a SPA consistent with the extended compliance deadline.

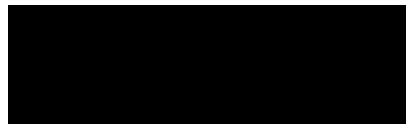
State Plan Amendments

States will need to submit a new SPA at section 3.1A and 3.1B to effectuate this new coverage requirement under section 1905(a)(30), effective with respect to items and services furnished on or after January 1, 2022, unless the exception for state legislation described above applies. Additionally, a state will need to submit a SPA at section 4.19(b) to describe payment methodologies that will be used to pay service providers. Changes in methods and standards for payments associated with the 4.19(b) SPA are subject to the public notice requirements at 42 CFR §447.205, which must be issued at least one day prior to the effective date of the proposed changes. These SPAs are needed to ensure that the state is appropriately covering and paying for routine patient costs of items and services for beneficiaries enrolled in qualifying clinical trials,

as newly required under amendments made by section 210. Similarly, states will need to submit ABP SPAs to add this coverage to their ABPs. ABP SPA public notice requirements under 42 CFR §440.386 must be followed. CMS is available for technical assistance on SPA submissions. States using a managed care delivery system should also evaluate their managed care plan contracts and capitation rates to determine the need for potential revisions with respect to items and services furnished to Medicaid beneficiaries on or after January 1, 2022, such as whether to carve out such costs so the state would provide them outside the scope of the contract or include appropriate amounts in capitation rates to cover an obligation to cover the out of network costs.

For additional information, please contact Kirsten Jensen, Director, Division of Benefits and Coverage, at Kirsten.Jensen@cms.hhs.gov.

Sincerely,



Daniel Tsai
Deputy Administrator and Director