

## Introduction

On December 21, 2020, the President of the United States signed into law the Consolidated Appropriations Act, 2021 (CAA). Section 210 of the CAA 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 enrollee participation in a qualifying clinical trial.

Addressing disparities in cancer care, including in clinical trial enrollment, has long been a priority for ASCO, and we applaud congress for passing the CLINICAL TREATMENT Act. The Centers for Medicare and Medicaid Services (CMS) and states can implement the CLINICAL TREATMENT Act through a State Plan Amendment (SPAs). We believe this will improve diversity in clinical trials, help prevent barriers for Medicaid enrollee participation in clinical trials and create coverage and reimbursement policy which is consistent across states and territories. More importantly, using SPAs, and clear and comprehensive SPA guidance/template for implementation will help ensure equitable, comprehensive, broad, transparent, and consistent access across states, which is important for cancer patient care and the results of clinical trials.

Clinical trials are critical to advancing progress against cancer, as treatments become increasingly tailored to precise patient or tumor characteristics. For patients who are not responding to existing cancer treatments, clinical trials may be the only option with the potential to slow or stop the course of disease, potentially providing them with additional months or even years of life.

Participation levels in cancer clinical trials has historically been far lower and less diverse than the actual demographics of patients living with cancer and the prevalence of the disease. Racial and ethnic minority populations, sexual and gender minorities, and older adults are all dramatically underrepresented in clinical trials, often despite equal or higher cancer incidence rates compared to the general population.<sup>1,2,3</sup> Recent analyses of cancer therapeutic trials found that only 4% to 6% of trial participants are Black and 3% to 6% are Hispanic, despite representing 15% and 13% of all patients with cancer, respectively.<sup>4</sup>

There are a variety of reasons for the lack of diversity in trial participants, including narrow eligibility criteria and other study design barriers; challenges with access, insurance coverage, and cost of care; awareness about trials; a lack of trust in the healthcare system and/or clinical research; linguistic,

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<sup>1</sup> Duma, Narjust, et al. "Representation of minorities and women in oncology clinical trials: review of the past 14 years." *Journal of oncology practice* 14.1 (2018): e1-e10.

<sup>2</sup> Murthy, Vivek H., Harlan M. Krumholz, and Cary P. Gross. "Participation in cancer clinical trials: race-, sex-, and age-based disparities." *Jama* 291.22 (2004): 2720-2726.

<sup>3</sup> Hutchins, Laura F., et al. "Underrepresentation of patients 65 years of age or older in cancer-treatment trials." *New England Journal of Medicine* 341.27 (1999): 2061-2067.

<sup>4</sup> Duma, Narjust, et al. "Representation of minorities and women in oncology clinical trials: review of the past 14 years." *Journal of oncology practice* 14.1 (2018): e1-e10.

cultural or literacy-related barriers; and factors such as family and community engagement.<sup>5,6,7,8,9</sup> Underrepresentation results not only from failure to enroll patients in trials but also from a lack of retention of minority populations while on study.<sup>10</sup> Diversifying clinical trial participation will address multiple areas of concern: improving the overall conduct of clinical research, improving the evidence base for high-quality cancer care, and helping to resolve health concerns related to underrepresentation in clinical trials.

ASCO believes improving the diversity of clinical trial participants will benefit all cancer care stakeholders and should be prioritized. The passage of the CLINICAL TREATMENT ACT is one of many opportunities to improve the diversity of clinical trials participants; therefore, we strongly ask CMCS to implement section 210 of the CAA as broadly and comprehensively as the legislation allows, and as we have proposed in the State Plan Amendment template. ASCO is committed to working with CMCS to significantly increase Medicaid beneficiary access and the diversity of clinical trials participants through the thoughtful implementation of the CLINICAL TREATMENT Act.

For additional information please read ASCO's Improving Diversity in Clinical Trial Participation [policy brief](#).

This Challenges and Rationale document follows roughly the same outline as the SPA template and provides rationale for specific recommendations included in the SPA. ASCO members with deep connections to and work experience with clinical trials have shared stories and scenarios documenting the successes and challenges they have encountered enrolling patients in clinical trials. We would like to work with CMS to address potential challenges and to roll out a smooth implementation bringing potentially life-saving therapies through clinical trial access to the 79 million<sup>11</sup> Medicaid beneficiaries in the United States.

## Section A – Definitions

### *Qualifying Clinical Trial*

“The phrase “qualifying clinical trial” shall refer to a phase 0, I, II, III, or IV clinical trial for devices, technologies, biologics, imaging, radiation therapy, surgeries or other modalities, behavior change,

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<sup>5</sup> Adams-Campbell, L.L., et al., Enrollment of African Americans onto clinical treatment trials: study design barriers. *Journal of Clinical Oncology*, 2004. 22(4): p. 730-734.

<sup>6</sup> Wynia, M.K. and V.N. Gamble, Mistrust among Minorities and the Trustworthiness of Medicine. *PLOS Medicine*, 2006. 3(5): p. e244.

<sup>7</sup> Nipp, R.D., et al., Recognizing the financial burden of cancer patients in clinical trials. 2015, AlphaMed Press.

<sup>8</sup> Unger, J.M., et al., Patient income level and cancer clinical trial participation: a prospective survey study. *JAMA oncology*, 2016. 2(1): p. 137-139

<sup>9</sup> Ford, J.G., et al., Barriers to recruiting underrepresented populations to cancer clinical trials: a systematic review. *Cancer*, 2008. 112(2): p. 228-242.

<sup>10</sup> Arnold, K.B., et al., Retention of black and white participants in the selenium and vitamin E cancer prevention trial (SWOG-coordinated intergroup study S0000). *Cancer Epidemiol Biomarkers Prev*, 2014. 23(12): p. 2895-905.

<sup>11</sup> <https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html#:~:text=78%2C900%2C421%20individuals%20were%20enrolled%20in,individuals%20were%20enrolled%20in%20Medicaid>.

drugs, procedures, items, or services involving the prevention, detection, or treatment of cancer or other life-threatening disease or condition if one or more of the following conditions apply.

Medicaid coverage for the routine costs of care applies to any clinical trial that meets the statutory definition of a qualifying clinical trial. The statute does not exclude any specific types of trials, i.e., those for devices, biologics etc. To ensure clarity, prevent unnecessary denials and promote consistency across states, we urge CMS to specifically state each category of clinical trial as written in the ASCO definition on the SPA template.

The legislation states that Medicaid is required to cover the routine costs of care for trials in “any stage of development”. We recommend that CMS, in the definition of qualifying clinical trial, list the five phases of clinical trial development: Phase 0, Phase I, Phase II, Phase III, Phase IV to eliminate any uncertainty in Medicaid coverage. Lack of clarity in the Medicare NCD and variability of coverage across other payers could lead to confusion regarding coverage in Medicaid. Phase I clinical trial studies are used by researchers to determine the recommended dose and safety of an investigational agent. Patient participation in phase I clinical trials have benefited from improved quality of life, improved psychological and medical benefits. Including phase I clinical trials in Medicaid has the potential to increase diversity of participants in the early phases of clinical trials. Read [here](#) for greater detail on phase I clinical trials and the associated patient benefits.

#### *Routine cost of care:*

ASCO recommends this section be clear that all services typically covered under a Medicaid plan and/or through a waiver, as listed on the Medicaid fee schedule, will be covered regardless of whether they are offered as part of a clinical trial or as standard care. We have heard from members with concerns that depending on how the guidance is written, circumstances could arise when Medicaid could theoretically only cover a portion of the routine care or situations in which standard care would not be covered. For example, if the clinical trial is for a new drug, Medicaid may consider the administration of the drug as routine care but not the imaging or evaluation and management services that accompany a trial. We recommend that the guidance be as clear as possible that all covered Medicaid services will be reimbursed, regardless of whether they are routine or standard care.

## **Section B – Coverage**

### *Requirements for State Medicaid Coverage of Routine Costs*

As mentioned in the definition section above, one significant flaw in the Medicare national coverage determination (NCD) is the absence of coverage for phase I trials resulting in lack of coverage or excessive challenges in getting coverage of phase I clinical trials. This challenge exists because there is a requirement in Medicare NCD that requires “therapeutic intent,” and there is not explicit reference in the Medicare NCD to “Phase I” trials. We strongly encourage CMS to include coverage for phase I clinical trials and not limit trials to those with “therapeutic intent” in the coverage policy.

If the clinical trial meets the criteria for coverage, the nature of the clinical trial (device, drug, procedure) is irrelevant, and Medicaid should cover the routine costs. As new technologies and services enter the

health care market, maintaining a wide scope of clinical trials will prevent state agencies from having to re-draft the SPA as new types of trials become available.

### *Prior Authorization*

Section 210 of the CAA requires that a determination of coverage for an individual participating in a qualifying clinical trial shall be expedited and completed within 72 hours. From the patient's perspective, the most critical, time-sensitive decision is whether the health plan or insurance issuer will provide coverage for routine costs associated with the trial. Prolonged prior authorization waiting periods can lead to significant barriers to care by delaying clinical trial enrollment and initiation of treatment, regardless of whether the treatment takes place as part of the study. Cancer patients, especially those in stage IV, are exceptionally vulnerable and they may not be able to wait for prolonged periods to access treatment whether through a trial or not. Additionally, clinical trials can fill up while a patient is waiting for a response from the insurer thus eliminating, in some cases, a patient's only option for treatment. While the statute requires a 72-hour response time, we ask CMS to give states the option to require an expedited prior authorization period, especially for those with a (stage III or IV) cancer diagnosis.

### **Section C – Eligibility**

As previously mentioned, often a cancer patient's ideal course of treatment is enrollment in a clinical trial. While we understand that CMS does not have the authority to mandate additional eligibility groups, we strongly urge CMS to highlight the two eligibility groups for patients (women) with cancer as an additional group that could potentially be listed to give these cancer patients access to this critical benefit and potentially life-saving interventions. #3 in the Eligibility section of the SPA template encourages states to cover Certain Patients (Women) Needing Treatment for Breast or Cervical Cancer and Presumptively Eligible Patients (Women) with Breast or Cervical Cancer eligibility groups. To increase the diversification of clinical trials as well as to improve access to clinical trials for all Medicaid cancer patients we urge CMS to encourage states to include additional eligibility groups through the SPA. The bullets in number four allow states space to note the additional covered categories.

### **Section D – Benefits**

#### *Routine Care 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. It is often unclear to health plans what is considered routine care and standard care, and lack of understanding and transparency can lead to denied services. One specific example we have heard from our members is that Electrocardiograms (EKGs) are done at screening and are only covered if the patient has signs and symptoms, so this is done as part of a trial with no sign/symptoms it would not be covered under Medicaid, and the hospital is not reimbursed for the cost of the service.

To reduce plan, provider, and billing confusion regarding what is considered routine care and to make clear that these services will be covered regardless of clinical trial participation, we recommend that CMS, in addition to stating the aforementioned, explicitly state the covered services frequently billed, as a consequence of the treatment, for patients participating in a clinical trial. The list of services we have included in the SPA are those typically performed in association with clinical trials and should be considered a minimum. Routine care should not be limited to only these services.

To obviate a state's need to annually update this SPA, we recommend using the language included in the fourth bullet of this section. This will ensure that any new billable item, procedure, device, or service available in the year the clinical trial takes place may be covered as routine care and cannot be denied coverage and reimbursement.

#### *Drug Benefit:*

Although Medicaid plans must cover nearly all prescription drugs through the Medicaid drug rebate program, states can limit access to drugs through actions such as prior authorization and quantity limits. In this SPA, we recommend that CMS require states to remove any restrictions on access to supportive care drugs. Supportive care drugs minimize the side effects of the toxic therapies used to treat cancer and play a crucial role in a patient's quality of life. If a cancer patient does not have the necessary supportive care drugs, due to insufficient quantity or a delay in acquisition, the patient is less likely to tolerate the harsh treatment and fail to complete the full course of therapy. Restricting access to supportive care drugs will certainly result in worsening quality of life and health outcomes as well as the potential to interfere with study results.

#### *Transportation Benefit*

We ask CMS to include this section in the SPA to make it undeniably clear that Medicaid beneficiaries may use their existing non-emergency medical transportation (NEMT) coverage to access all clinical trial related appointments. Low-income, elderly, and racial and ethnic minority populations disproportionately report lack of reliable transportation and other transportation related challenges resulting in decreased care, and in this case would leave them without access to clinical trials. By reasserting that this benefit applies to clinical trial appointments and routine care, we would expect that this could increase access for underserved populations.

Currently, Iowa, Utah and Indiana have a waiver disallowing this NEMT benefit in certain situations. We would like to discuss with CMS how they intend to address this and what the possibilities are to give beneficiaries in these states access to NEMT for clinical trials.

#### *Geography*

Individuals with cancer are ill-equipped to travel long distances to secure cancer care in large part due to the nature of their illnesses and painful anticancer treatment regimens. This burden is amplified for low-income individuals, who have even greater difficulty due to the costs associated with transportation, hotels, food, and other expenses incurred when traveling. Requirements to travel long distances are likely to exacerbate disparities in access to clinical trials. For this reason, it is imperative that a Medicaid

enrollee have access to the nearest clinical trial, regardless of the state in which the trial takes place.

### *Site of Service*

To ensure that Medicaid beneficiaries have access to necessary routine services in a location that is most convenient for them, we ask CMS to clearly state that the qualifying individual may receive routine care at any Medicaid facility or non-facility setting at which the service may be provided. One way in which states may try to limit coverage is by restricting the locations at which an enrollee may receive routine care. To reduce barriers previously discussed, such as lack of transportation and the inability for cancer patients to travel long distances, we encourage CMS to state clear requirements.

Understanding that telehealth coverage varies by state, we would like to discuss with CMS how best to encourage states to promote coverage and reimbursement for routine care in the SPA template or through implementation guidance. Telehealth has become an integral part of care delivery, for both patients and providers, and ASCO strongly supports robust telehealth coverage.

### *Cost-Sharing*

We recommend that CMS waive cost sharing requirements for routine care during enrollment in clinical trials. Medicaid beneficiaries have limited resources to spend on out-of-pocket health costs. Even relatively low amounts can cause Medicaid beneficiaries to forgo necessities such as food, clothing, and health care services. Studies have shown that these relatively small cost sharing requirements are associated with reduced levels of care leading to decreased health outcomes. Additionally, research shows that potential revenue gains from cost sharing are offset by increased use of more expensive services, such as emergency room care among others.<sup>12</sup> Medicaid beneficiaries, who are often low-income individuals, experience increased challenges in meeting daily needs. CMS has the opportunity to ease barriers to care for vulnerable beneficiaries, promoting equitable access to life-saving treatments through this guidance.

## **Section E – Reimbursement for Routine Care**

### *Reimbursement*

Because routine costs are expected to be the same items, services, and procedures are already covered under the Medicaid state plan or through a waiver, this SPA does not require a section to establish reimbursement methodology. The purpose of this section is to state clearly that the routine costs are equal to the rate the state has already established in the fee schedule for that service. Routine care costs are not to exceed rates that are already established, nor should they be lower than the published rate to ensure equitable access and maintain continuity within the Medicaid program for both providers

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<sup>12</sup> <https://www.kff.org/medicaid/issue-brief/the-effects-of-premiums-and-cost-sharing-on-low-income-populations-updated-review-of-research-findings/>

and beneficiaries.

### *Coding and Billing*

Challenges in coding and billing for routine care associated with clinical trials has the potential to significantly restrict beneficiary access to clinical trials and the associated routine care. Members have repeatedly shared stories of instances when incorrect coding results in a patient being released from a clinical trial even if the health system covers the cost and Medicaid is not held financially responsible. There are also examples of patients being forced to drop out of trials because routine costs are denied as a result of billing errors. We are aware of clinical trial sites that avoid enrolling Medicaid patients because of complicated and unclear billing practices, resulting in loss of revenue at the clinical trial site or increased participant attrition rates. Administrative challenges as billing and coding should not become a barrier for Medicaid patients to access their newly guaranteed benefits.

The SPA template aims to keep coding and billing as simple as possible with minimal opportunity for denials to occur while maintaining the ability to collect data on clinical trial participation in Medicaid. If a patient is on a clinical trial, the clinical trial identifier and the ICD-10 diagnosis code indicating the participant is enrolled in a clinical trial must be present on the claim. Physicians may bill standard care and routine care on the same claim; however, the modifier X1 must be included on every claim line for a service performed as routine care. All claim lines, those with and without an X1 modifier, will be covered and reimbursed at the established rate in that setting. We strongly advise that CMS make it clear routine costs are covered and reimbursed at the same rate as indicated under the state plan's fee schedule, and that they will be covered whether the patient is on a trial or not. Consistent with Medicare billing, items and services provided free of charge by the research sponsors do not need to be documented on the Medicaid claim.

The ideas we have presented in this draft SPA suggest some strategies for ensuring that billing and coding do not prevent access to care for life-threatening conditions like cancer. We would like to explore these or other possible approaches with CMS as it shapes implementation policy for this important benefit.

### **Section F – Communication**

A common concern voiced by individuals with cancer and health care providers is that unnecessary complexity exists in information about whether an individual's health plan covers routine care costs associated with clinical trial participation. Often this information is not published on the plan website or its print materials and can only be determined through submission of a formal request. Not only is this burdensome for individuals diagnosed with life threatening illnesses, but it also prevents healthy individuals from making informed choices when selecting a health plan.

As discussed in the opening paragraphs, awareness of clinical trials and linguistic, cultural or literacy-related barriers often discourage patient participation in clinical trials, resulting in failure to enroll. For these reasons we ask that CMS require states to supply education materials and for these documents to be written at no higher than a 6<sup>th</sup> grade reading level. Under any scenario, individuals should be able to refer to unambiguous, clear explanations about how to access this new benefit.

In addition to clear and easy to understand communications regarding Medicaid coverage of routine care, ASCO supports the expansion of patient navigator programs, as they have the potential to increase

participation and retention of minority patients in clinical trials.<sup>13</sup> Without targeted communication strategies in place to alert patients to the opportunity for clinical trial participation, Medicaid beneficiaries may not be likely to enroll in clinical trials. Establishment of a patient navigator program could be a tremendous opportunity to remove obstacles for underserved populations who may not independently seek to enroll in clinical trials. Section 210 of the CAA does not grant CMS the authority to require states to establish such a patient engagement initiative; however, we strongly recommend that CMS provide states information supporting the establishment of and implementation guidance for a patient navigator program. ASCO would be willing to collaborate and lead this effort by working together to develop training and informational materials for states.

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<sup>13</sup> Ghebre RG, Jones LA, Wenzel JA, Martin MY, Durant RW, Ford JG. State-of-the-science of patient navigation as a strategy for enhancing minority clinical trial accrual. *Cancer* 2014; 120: Suppl 7: 1122-30.