Chapter 7 Section 24.2

Coronavirus Disease 2019 (COVID-19) Clinical Trials

Issue Date: December 9, 2020
Authority: 32 CFR 199.4(e)(26)

1.0 DESCRIPTION

On October 30, 2020, the Department of Defense (DoD) published an Interim Final Rule (85 FR 68753) that authorizes Defense Health Agency (DHA) coverage of drugs, devices, and medical treatments or procedures provided in clinical trials sponsored by National Institute of Allergy and Infectious Diseases (NIAID) for the prevention or treatment of COVID-19. These regulatory provisions enforce an agreement between DoD and the National Institutes of Health (NIH), executed September 19, 2020, both of which authorize DoD cost-sharing of care provided in connection with NIH sponsored or approved clinical trials and establishes requirements and responsibilities for both parties.

2.0 POLICY

2.1 COVID-19 clinical trial participation is authorized for those TRICARE-eligible patients selected to participate in NIAID-sponsored Phase I, II, III, and IV studies for the prevention, screening, early detection, and treatment of COVID-19 and its associated sequelae (e.g., cardiac and pulmonary complications). TRICARE will cost-share all medical care and testing required to determine eligibility for an NIAID-sponsored trial, including the evaluation for eligibility at the institution conducting the NIAID-sponsored trial. TRICARE will cost-share all medical care required as a result of participation in NIAID-sponsored studies, including necessary follow-up care and testing that takes place after the period of active treatment on protocol is completed. This includes purchasing and administering all approved pharmaceutical drugs (except for the NIAID-funded investigational agents) and all inpatient and outpatient care, including diagnostic, laboratory, rehabilitation, and home health services not otherwise reimbursed under an NIAID grant program, if the following conditions are met:

2.1.1 Such treatments are NIAID-sponsored Phase I, Phase II, Phase III, or Phase IV protocols (see paragraph 3.1);

2.1.2 The patient continues to meet entry criteria for said protocol;

2.1.3 The institutional and individual providers are TRICARE-authorized providers.

2.2 In addition to the above requirements, the following conditions must be met for participation in Phase I COVID-19 clinical trials. Attending physician, Primary Care Manager (PCM), or specialist referral to the trial, and the beneficiary's subsequent acceptance to the trial fulfill these requirements.

2.2.1 Standard treatment has been or would be ineffective, does not exist, or there is no superior non-investigational treatment alternative; and

2.2.2 The available clinical or preclinical data provide a reasonable expectation that the treatment will be at least as effective as the non-investigational alternative; and

2.2.3 The facility and personnel providing the treatment are capable of doing so by virtue of their experience, training, and volume of patients treated to maintain expertise; and

2.2.4 The beneficiary's participation in such a trial would be appropriate based upon the satisfaction of the above criteria.

3.0 POLICY CONSIDERATIONS

3.1 Identification of Eligible Clinical Trials

3.1.1 There is no central repository for COVID-19 clinical trials eligible under this benefit. However, most clinical trials conducted in the United States are listed in the US National Library of Medicine Database at https://clinicaltrials.gov/. Trials listed in this database will indicate the topic of study (e.g., evaluating the efficacy of a COVID-19 vaccine) and the study sponsor and collaborators (e.g., NIAID). A trial is considered to meet the requirement for NIAID-sponsorship or approval if NIAID is listed as either the trial sponsor or a trial collaborator.

3.1.2 COVID-19 clinical trials may also be identified by searching the NIAID website at https://www.niaid.nih.gov/.

3.1.3 Clinical trials must meet the criteria in this section to be eligible under this benefit.

3.1.4 If there is any uncertainty about the eligibility of a clinical trial, then providers, contractors, and beneficiaries may contact NIH or NIAID directly.

3.1.5 Requests for treatment in COVID-19 clinical trials overseas must be verified as to NIAID sponsorship using the procedures described in paragraph 3.2.1.

3.2 Contractor Responsibilities

3.2.1 The contractors shall verify that the COVID-19 clinical trial is sponsored by NIAID and otherwise meets all requirements of this section. If the contractor is unable to ascertain the NIAID-sponsorship status of a clinical trial at either clinicaltrials.gov or the NIAID website, the contractor shall obtain the trial sponsorship status via other means including contacting NIAID, NIH, the trial investigators, and the provider submitting the claim. The contractor shall not deny coverage of a beneficiary claim for participation in a COVID-19 clinical trial based solely on information obtained from clinicaltrials.gov or the NIAID website.

3.2.2 The contractors shall verify that all services and supplies that are submitted for cost-sharing meet the requirements of this section.

3.2.3 The contractors may at their discretion establish a dedicated toll-free telephone number to receive inquiries from both patients and providers regarding the COVID-19 clinical trials benefit,

or may use the dedicated cancer clinical trial toll-free telephone number, if available. If a dedicated toll-free telephone number is established, the phone shall be staffed seven hours a day during normal business hours in the contractors' time zones where the inquiries are received. In the absence of a dedicated toll-free number for COVID-19 clinical trials or cancer and COVID-19 clinical trials benefit inquiries, contractors shall use their primary toll-free telephone inquiry system (see the TRICARE Operations Manual (TOM), Chapter 11, Section 6 and Chapter 20, Section 4).

3.3 The DoD has no authority regarding the NIAID protocol eligibility for the sponsored study. Therefore, if a patient does not meet the protocol eligibility criteria for enrollment, appeal rights do not apply.

3.4 Claims will be submitted and paid through normal TRICARE Encounter Data (TED) system processing as required in the TRICARE Systems Manual (TSM) with the applicable coding for COVID-19 clinical trials with enrollment in Phase I, II, III, and IV COVID-19 clinical trials.

3.5 Normal TRICARE eligibility, reimbursement, co-payments, cost-shares, deductibles, TRICARE for Life (TFL), and double coverage rules apply.

4.0 EXCLUSIONS

4.1 Care rendered in the NIH Clinical Center.

4.2 Costs associated with non-treatment research activities associated with the clinical trials. These include, but are not limited to: data collection activities, management and analysis of the data, salaries of the research nurses, and the cost of the investigational agents (if used in the protocol). These research costs will also not be the responsibility of the beneficiaries participating in the clinical trials.

4.3 Trials not meeting the requirements of this section are excluded, for example, industry-sponsored trials where NIAID is not a sponsor or collaborator.

5.0 EFFECTIVE DATE

Effective October 30, 2020.

5.1 Coverage for COVID-19 clinical trials will last through the end of the President's national emergency.

5.2 Beneficiaries who have been enrolled in an eligible COVID-19 clinical trial during the national emergency will continue to have their care covered for the duration of that clinical trial, even if the national emergency has ended, so long as the requirements of this section are met.

- END -