Clinical Trials Frequently Asked Questions (FAQ)

Providers are required to submit the attestation for any client enrolled in a clinical trials as of July 1, 2022.

Q. What is a "qualifying clinical trial?"

A. A trial related to "the prevention, detection, or treatment of any serious or life-threatening disease or condition." This includes a trial funded by the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), or other federal-approved entities. (Refer to SSA § 1905(gg)(2)(A).)

Q. Who determines that the clinical trial is a "qualified" trial? Can the MCO determine that on our own or do we need HCA to approve?

A. The MCOs are to conduct their own medical necessity determinations. The information for what is considered a qualified clinical trial can be found at https://www.medicaid.gov/federal-policy-guidance/downloads/smd21005.pdf

Q. Are the MCOs required to seek out a completed form if the provider doesn't submit it?

A. Yes, attestation forms should be available upon an audit request or for TEAMonitoring (however it might be difficult to know if a client is/was on a trial if the attestation form wasn't sent in to begin with)

Q. Are providers required to submit an attestation form *even if* they didn't request an authorization for services associated with the clinical trial?

A. Yes, all clinical trials require an attestation form.

Q. Should providers submit an attestation form with each prior authorization (PA) request associated with the same trial or just the initial request?

A. Providers do not need to submit the attestation form with each PA request.

Q. Do our providers submit the attestation form to the MCO or to HCA?

A. Providers should send the attestation form to the MCO.

Q. Do the MCOs complete the attestation form or does the provider?

A. Providers are to complete the attestation form and submit to the MCOs.

Q. If the MCOs have to submit to the HCA, does that have to happen before the member can start the clinical trial or can they start once the MCO approves?

A. The form does not need to be sent to HCA unless requested.

Q. Will HCA require reporting of members enrolled in clinical trials?

A. Yes, we are working on a template and will require quarterly reporting.

MCOs must ensure a coverage determination is completed within 72 hours.

Q. Can the MCOs extend the 72-hour timeframe to request additional clinical and/or the attestation form if not submitted at the time of request?

A. Yes, the timeframe can be extended if the appropriate materials are not submitted. Each time the plan has to request additional information, the "clock" is reset to 72 hours.

Q. Does HCA have a plan for identifying clinical trial requests upon receipt to ensure timeliness? IE: requiring providers to include "Clinical Trial" on the request form, etc.

A. HCA will not be requiring prior authorization for the clinical trial. HCA is seeking further technical assistance from CMS to determine if any services requiring prior authorization (PA) that are related to a clinical trial, such as an MRI – will the 72-hour rule apply. If it does HCA will update our billing guide with further instructions. At this time, our legal counsel is advising that all PAs for clients that are on a clinical trial be subject to the 72-hour rule. We have instructed providers to indicate on the first page of the request that it is an urgent request, associated with a clinical trial.

Q. The HCA Billing Guide does not mention the 72-hour requirement, do the MCOs have to approve the clinical trial in 72-hours or does the MCO do that approval for our providers/members?

A. See answers to previous question. The MCOs shall conduct their own reviews and provide a decision in 72-hours.