



PHYSICIAN CERTIFICATE OF ATTESTATION

CERTIFICATION OF ROUTINE COSTS ASSOCIATED WITH PARTICIPATION IN A QUALIFYING CLINICAL TRIAL

Instructions for use:

This Physician Certificate of Attestation must be completed only by the physician requesting approval of routine costs associated with a qualifying clinical trial. Failure to complete this form in its entirety may result in its return to the physician for appropriate documentation and signatures and a delay in the evaluation of the attestation and attachments. All field-completions (eg, checked boxes, initials) and signatures requested in this form must be completed. Completion, signature, and submission of this form is a certification that the services being requested meet all requirements for coverage of routine costs associated with qualifying clinical trials.

Submission Instructions:

- Complete and sign the form and include additional documents as indicated.
- Fax the completed form and required attachments to the Care Management and Coordination Department at (215) 761-0257. Hours are 8:00 a.m. to 5:00 p.m., Monday through Friday.

Physician's Name (Please Print):
Physician's NPI #:
Physician's Office Contact Name (if different from physician):
Office/Contact Phone #:
Trial Sponsor:
Trial Name:
ClinicalTrials.gov Identifier # (NCT Number):
Patient's Name (please print):
Patient's Member ID#:
Patient's Date of Birth:

<p>Please Initial Here: _____</p>	<p>By completing and signing below, I certify that the services being requested meet the requirements listed in this document:</p> <ul style="list-style-type: none"> • Please initial or check (<input checked="" type="checkbox"/>) the space or box associated with each section to certify that the requirements for that section are met.
<p>Please Initial Here: _____</p> <p>Please Read and Check All Boxes</p> <p><input type="checkbox"/> A</p>	<p>Services are being requested for a qualifying clinical trial that meets all of the following requirements:</p> <p>The qualifying clinical trial has a therapeutic intent for enrolled patients with a diagnosed disease. The qualifying clinical trial has a principal purpose to discern whether the service improves health outcomes for enrolled patients with a diagnosed disease.</p> <ul style="list-style-type: none"> • Services are not approvable for the following because they do not meet this requirement: <ul style="list-style-type: none"> ○ Participants without disease (eg, normal volunteers or controls) ○ Participants ineligible for the trial ○ Participants treated “off-protocol” ○ Participants in Phase I clinical trials <ul style="list-style-type: none"> ▪ This does not apply to members of NJ Groups that allow coverage of routine costs associated with Phase I cancer clinical trials in accordance with the voluntary agreement developed by the New Jersey Working Group to Improve Outcomes in Cancer Patients (WGIOC) ○ Participants in a Phase II clinical trial that is designed exclusively to test toxicity or disease pathophysiology <ul style="list-style-type: none"> ▪ This does not apply to members of NJ Groups that allow coverage of routine costs associated with Phase II cancer clinical trials in accordance with the voluntary agreement developed by the New Jersey Working Group to Improve Outcomes in Cancer Patients (WGIOC)
<p><input type="checkbox"/> B.</p>	<p>The qualifying clinical trial is intended to clarify or establish health outcomes of interventions already in common clinical use as defined by the available evidence.</p>
<p><input type="checkbox"/> C.</p>	<p>The qualifying clinical trial does not duplicate existing studies.</p>
<p><input type="checkbox"/> D.</p>	<p>The qualifying clinical trial is designed to collect and disseminate reliable evidence, as defined in the Company policy on Routine Costs Associated with Qualifying Clinical Trials, and answer specific research questions being asked in the trial.</p>
<p><input type="checkbox"/> E.</p>	<p>The qualifying clinical trial is designed and conducted according to appropriate standards of scientific integrity (such as, but not limited to: there is a beginning and an endpoint to the study; there is a specific number of potential enrollees; the patient accrual period is clearly defined; informed consent is provided to all enrollees; appropriate approvals, patient selection, and exclusion criteria are well-defined; a written protocol outlining all these points exists).</p>
<p><input type="checkbox"/> F.</p>	<p>The trial complies with federal regulations relating to the protection of human subjects.</p>

Please read the following benefit information (G. and H.) and initial the benefit that applies to the trial participant:

Please Initial Here: _____

G. For participants who are members of NJ Commercial groups that provide benefits for routine costs associated with Phase I, Phase II, and Phase III **cancer** clinical trials in accordance with the voluntary agreement developed by the New Jersey Working Group to Improve Outcomes in Cancer Patients (WGIOC) and sponsored by the NJ Association of Health Plans both of the following apply:

Please Read and Check All Boxes

- 1. The cancer clinical trial is conducted in the State of NJ
- 2. The cancer clinical trial must be approved by an Institutional Review Board (IRB) and one of the following institutions:
 - National Cancer Institute (NCI)
 - National Institutes of Health (NIH)
 - Research arm of the Department of Defense (DOD)
 - Department of Veterans Affairs (VA)

US Food and Drug Administration (FDA), or has an investigational new drug (IND) exemption as defined by the US Food and Drug Administration (FDA)

OR

Please Initial Here: _____

H. For members of all other Commercial products that include benefits for routine costs associated with a qualifying clinical trial, one of the following applies:

Please Initial Here: _____ 1. The trial is conducted under an investigational new drug application reviewed by the FDA, or an investigational new drug exemption as defined by the FDA.

Please Initial Here: _____ 2. The trial is funded by, or supported by centers or cooperative groups that are funded by any one of the following:

Please Check 1:

- The National Institutes of Health (NIH)
- Centers for Disease Control and Prevention (CDC)
- Agency for Healthcare Research and Quality (AHRQ)
- Centers for Medicare and Medicaid Services (CMS)
- A research arm of the Department of Defense (DOD)
- Department of Veterans Affairs (VA)

ALL OF THE FOLLOWING FIELDS APPLY TO ALL ELIGIBLE PRODUCTS

Please Initial Here: _____ Services and supplies requested are routine costs, which include the following:

- A. Covered services under the individual's product that would typically be provided absent a qualifying clinical trial.
- B. Services and supplies required solely for the provision of the biological product, device, drug, medical treatment, procedure, or therapy under investigation in the clinical trial.
- C. The clinically appropriate monitoring of the effects of the biological product, device, drug, medical treatment, procedure, or therapy under investigation in the clinical trial that is required for the prevention of complications.
- D. The services and supplies required for the diagnosis or treatment of complications.

Please Initial Here: _____ The routine costs (services and supplies) requested do not include:

- A. The biological product, device, drug, medical treatment, procedure, or therapy under investigation in the qualifying clinical trial (ie, the experimental/investigational service itself)
- Experimental/investigational is defined by the individual's product or plan
- B. Services and supplies provided for data collection and analysis or submission.
- C. Services and supplies customarily provided by the research sponsors free of charge to any enrollees.
- D. Any services that the member's plan does not routinely cover such as, but not limited to services that:
- The plan deems to be experimental/investigational
 - Have met or exceeded applicable benefit limitations described in the member contract
 - Are a benefit contract exclusion
 - Are deemed not medically necessary

Please Initial Here: _____	ALL OF THE FOLLOWING DOCUMENTS MUST BE INCLUDED:
Please Initial Here: _____	<p>A Letter of Medical Necessity outlining the specific services requested. At a minimum, this document must include:</p> <p>Please Check Each:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Narrative name of requested services <input type="checkbox"/> Applicable CPT/HCPCS codes for requested services <input type="checkbox"/> Number of services requested <input type="checkbox"/> Approximate dates of requested services <input type="checkbox"/> Name and address of any facility(ies) where services will be performed <input type="checkbox"/> The expected duration of participation in the trial, etc. <input type="checkbox"/> Any relevant clinical information <input type="checkbox"/> The Trial Protocol (including eligibility criteria for participation in trial)
Please Initial Here: _____	I certify that the participant in this qualifying clinical trial meets the eligibility criteria defined in the attached protocol to participate.
Please Initial Here: _____	A copy of the signed informed patient consent form for participation in the qualifying clinical trial from the trial sponsor is attached.

Please complete the following fields:	
Physician's Name (please print)	
Physician's Signature:	Date:

For more information on Routine Costs Associated with Qualifying Clinical Trials, please see medical policy 07.00.20 on this topic. [View the Medical Policy site >](#)