



NCI Cancer Trials (effective 5/1/11)

Effective immediately USFHP members may be eligible to participate in National Cancer Institute (NCI) sponsored Phase I Trials; this is a new benefit. Previously, only NCI sponsored Phase II and Phase III trials were available benefits. Participation in NCI sponsored Phase I, Phase II and Phase III trials always require pre-authorization and medical necessity review. All members approved to participate in an NCI sponsored Phase I, Phase II or Phase III trial will be referred for case management evaluation.

Benefit: yes (see also Investigational)

Authorization: yes and include

Co-payment: some members may be responsible for co-pay for covered services.

CPT code(s): various

HCPCS code(s): N/A

Description: Cancer clinical trial participation may be authorized for participation in National Cancer Institute (NCI) sponsored Phase I, Phase II and Phase III studies for the prevention, screening, early detection and treatment of cancer.

Specific considerations as part of the pre-authorization process:

- Documentation that proposed treatment(s) are NCI sponsored Phase I, Phase II or Phase III protocols.
- Patient meets criteria for said protocol, initial and during trial.
- Standard treatment has been or would be ineffective, does not exist, or there is no superior non-investigational treatment alternative. This requirement is fulfilled by attending physician, PCP or oncologist referral to the trial and the patient's subsequent acceptance to the trial fulfill this requirement.
- The available clinical or preclinical data provide a reasonable expectation that the treatment will be at least as effective as the non-investigational alternative. Attending physician PCP or oncologist referral to the trial and the patient's subsequent acceptance to the trial fulfill this requirement.
- 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. NCI sponsored trials meet this criteria.
- The patient's participation in such a trial would be appropriate based on the satisfaction of the above criteria. Attending physician, PCP or oncologist referral to the trial and the patient's subsequent acceptance to the trial fulfill this requirement.

Members approved for participation in NCI trials will be referred for case management evaluation.

Exclusion(s): Care rendered in the National Institutes of Health Clinical Center. Costs associated with non-treatment research activities related to clinical trials.

Reference(s): [TRICARE policy manual, chapter 7, section 24.1](#)