

<b>HEALTH PLAN POLICY</b>	
<b>Policy Title:</b> Prior Authorization for National Cancer Institute Clinical Trials	<b>Policy Number:</b> MUM03 <b>Revision:</b> F
<b>Department:</b> Medical Management	<b>Sub-Department:</b> Utilization Management
<b>Applies to Product Lines:</b> <input type="checkbox"/> Medicaid <input checked="" type="checkbox"/> USFHP <input type="checkbox"/> Children’s Health Insurance Plan <input checked="" type="checkbox"/> Commercial Insured <input checked="" type="checkbox"/> Health Insurance Exchange <input type="checkbox"/> Non Insured Business <input checked="" type="checkbox"/> Medicare	
<b>Origination/Effective Date:</b> 08/26/2014	
<b>Reviewed Date(s):</b>	<b>Revision Date(s):</b> 03/04/2016, 06/01/2017, 09/20/2018, 12/18/2019, 12/15/2020, 12/07/2021

**SCOPE:**

To assist health plan members in participating in National Cancer Institute (NCI) sponsored Phase I, Phase II or Phase III protocols and to ensure participation is reviewed and authorized in accordance with TRICARE policy and Medicare regulations.

**DEFINITIONS AND ACRONYMS:**

- **Clinical trials** - Clinical trials are research studies that involve people and test new ways to prevent, detect, diagnose, or treat cancer and other diseases.
- **National Cancer Institute (NCI)**
- **Phase I** - These trials are conducted to evaluate safety of chemical or biologic agents or other types of interventions (e.g., radiation therapy technique).
- **Phase II** – These trials test the effectiveness of interventions in people who have specific type of cancer or related cancers.
- **Phase III** – These trials compare effectiveness of new intervention, or new use of existing intervention, with the current standard of care for a particular type of cancer.

**POLICY:**

Members who are eligible for clinical trials will be identified to the health plan by the participating physician. The participating physician will provide the following to the health plan:

- The member’s name and last four digits of sponsor’s social security number.
- Request for authorization for services that specifies the clinical trial on the facility’s letterhead.
- Certification that the patient meets all entry criteria for the said protocol.
- Copy of NCI clinical trial protocol information.
- Proof of NCI Sponsorship.

Once received, the request for authorization will be subject to the authorization review process to include verification of clinical trial by utilizing NCI’s comprehensive cancer database, physician data query.

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The health plan will assign a utilization management registered nurse to work closely with the member, physician, and facility throughout the member's participation in the trial. The member will also be assigned to the case management team.

If the request meets TRICARE policy guidelines for approval, the authorization will be entered in the system and the requesting physician will be notified. If the request does not meet TRICARE policy guidelines it will be sent to the chief medical officer or designee for review and determination.

Medicare Advantage Generations members are free to participate in any qualifying clinical trial that is open to beneficiaries in original Medicare. The Medicare Advantage Organization (MAO) may not require prior authorization for participation in a Medicare-qualified clinical trial not sponsored by the plan, nor may it create impediments to an enrollee's participation in a non-plan-sponsored clinical trial. The MAO may request, but not require, enrollees to notify the Plan in advance when they choose to participate in a Medicare-qualified clinical trial.

### REFERENCES:

- National Cancer Institute: [www.cancer.gov/cancertopics/factsheet/clinicaltrials](http://www.cancer.gov/cancertopics/factsheet/clinicaltrials)
- Medicare Managed Care Manual, Chapters 6 and 11
- TRICARE Policy Manual 6010.60-M, Chapter 7, Section 24.1, 2015 Edition (T17)
- <http://www.cancer.gov/cancertopics/pdq/cancerdatabase>

### RELATED DOCUMENTS:

None

### REVISION HISTORY:

Revision	Date	Description of Change	Committee
New	08/26/2014	Initial Release	Board of Directors
A	03/04/2016	Yearly review – updated to current template. Updated Definitions and Acronyms.	Board of Directors
B	06/01/2017	Annual Review. Changed signatory from Anita Leal, Executive Director to Nancy Horstmann, CEO.	Board of Directors
C	09/20/2018	Annual review – corrected typos.	Executive Leadership
D	12/18/2019	Annual review. Updated Lines of Business, References, and miscellaneous verbiage throughout policy.	Executive Leadership
E	12/15/2020	Annual review. No change to policy content.	Executive Leadership
F	12/07/2021	Annual review. No change to policy content.	Executive Leadership