


| | | |
|---|--------------------------|---|
| No. UM-017 | Medicare Clinical Trials |  |
| Effective Date: 1/1/2020 | POLICY AND PROCEDURE | |
| Committee Approval: 1/11/23 | | |
| <p>CMS: Medicare Managed Care Manual Chapter 4 section 10.7 4/22/17</p> <p>DMHC TAG: Utilization Management, Terminal Illness Requirement and Compliance</p> <p>NCQA Standards: UM 2-7</p> | | |

Clinical Trials for Medicare Members

Medicare Members with a life-threatening or seriously debilitating condition or terminal illness may seek care through clinical trials or experimental or investigational therapies outside of clinical trials. “Life threatening condition” means either or both of the following: a) disease or conditions where the likelihood of death is high unless the course of the disease is interrupted, b) diseases or conditions with potentially fatal outcomes, where the endpoint of clinical intervention is survival. “Seriously debilitating” means diseases or conditions that cause major irreversible morbidity.

Experimental or Investigational Therapies

Medicare Members should be treated as any other member according to Canopy Health and full-service upstream Health Plan policies and requirements.

Clinical Trials

Before clinical trial enrollment: Canopy Health’s delegated medical groups/IPAs are responsible for members’ medical management, including referrals and authorizations for the clinical work up before clinical trial enrollment.

Authorization responsibility for clinical trials for Canopy Health Medicare members is managed by UnitedHealthcare (UHC). Upon receipt of request for clinical trial the medical groups/IPAs conduct the pre-trial workup and then contact UHC at 877-842-3210 and follow the instructions given by UHC. After review, UHC will either authorize or, if CMS has responsibility, forward the case to CMS. UHC is responsible for sending the follow up communication to the member and referring physician.

Financial responsibility is determined by contracts and CMS requirements. The medical groups/IPAs may retain financial responsibility for routine services during the trial.

Further information can be found under UHC's Medicare Advantage Coverage Summaries for Medicare Advantage.

Revision History:

| Version Date | Edited By | Reason for Change |
|--------------|-----------|-------------------|
| 01/01/2020 | R. Scott | Creation date. |