

~~OR PERMANENTLY DISABLING CONDITION TO THE EXTENT SUCH COSTS WOULD BE COVERED FOR NONINVESTIGATIONAL TREATMENTS IF:~~

~~(4) THE TREATMENT IS BEING PROVIDED WITH A THERAPEUTIC OR PALLIATIVE INTENT;~~

(D) A POLICY OR PLAN, PLAN, OR CONTRACT SUBJECT TO THIS SECTION SHALL PROVIDE COVERAGE FOR PATIENT COST TO A MEMBER IN A CLINICAL TRIAL, AS A RESULT OF:

(1) TREATMENT PROVIDED FOR A LIFE-THREATENING CONDITION; OR

(2) PREVENTION, EARLY DETECTION, AND TREATMENT STUDIES ON CANCER.

(E) THE COVERAGE UNDER SUBSECTION (D) OF THIS SECTION SHALL BE REQUIRED IF:

(1) (I) THE TREATMENT IS BEING PROVIDED OR THE STUDIES ARE BEING CONDUCTED IN A PHASE I, PHASE II, PHASE III, OR PHASE IV CLINICAL TRIAL FOR CANCER; OR

(II) THE TREATMENT IS BEING PROVIDED IN A PHASE II, PHASE III, OR PHASE IV CLINICAL TRIAL FOR ANY OTHER LIFE-THREATENING CONDITION;

(2) THE TREATMENT IS BEING PROVIDED IN ACCORDANCE WITH A CLINICAL TRIAL APPROVED BY:

(I) ONE OF THE NATIONAL INSTITUTES OF HEALTH;

(II) AN NIH COOPERATIVE GROUP OR AN NIH CENTER;

(III) THE FDA IN THE FORM OF AN INVESTIGATIONAL NEW DRUG APPLICATION;

(IV) THE FEDERAL DEPARTMENT OF VETERANS AFFAIRS;

~~(V) A QUALIFIED RESEARCH ENTITY THAT MEETS CRITERIA FOR NIH CENTER SUPPORT GRANT ELIGIBILITY; OR~~

~~(VI) A PANEL OF QUALIFIED RECOGNIZED EXPERTS IN CLINICAL RESEARCH WITHIN ACADEMIC HEALTH INSTITUTIONS IN THIS STATE;~~

~~(3) THE PROPOSED TREATMENT HAS BEEN REVIEWED AND APPROVED BY TWO QUALIFIED INSTITUTIONAL REVIEW BOARDS; OR~~

(V) AN INSTITUTIONAL REVIEW BOARD OF AN INSTITUTION IN THE STATE WHICH HAS A MULTIPLE PROJECT ASSURANCE CONTRACT APPROVED BY THE OFFICE OF PROTECTION FROM RESEARCH RISKS OF THE NATIONAL INSTITUTES OF HEALTH;

~~(4) (3) THE FACILITY AND PERSONNEL PROVIDING THE TREATMENT ARE PROVIDING THE TREATMENT WITHIN THEIR SCOPE OF PRACTICE, EXPERIENCE,~~