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Clinical Trial Coverage Analysis: Complying With Clinical Trial Policy

Medicare only pays for routine costs in qualifying clinical trials and the diagnosis and treatment of complications, as set forth in national coverage determination 310.1 ("Without Flags, Hospitals May Be Overpaid for Patients in Research," *RMC* 28, no. 9). To help ensure compliance, Lisa Murtha, senior managing director of Ankura Consulting Group, recommends hospitals perform a clinical trial coverage analysis. Contact her at lisa.murtha@ankura.com.

Clinical Trial Coverage Analysis				
PROTOCOL TITLE				
This coverage analysis is intended as a general guideline for use in determining which clinical research items and services are billable to third party payers based upon current benefit policies, coverage determinations, coverage decisions, and federal guidelines. All items and services that are billable to Medicare or other payer must be supported by medical necessity.				
Study Identifying Information				
Principal Investigator (PI):	Protocol Version Received:			
PI Contact info:	Informed Consent Version & Approval Date:			
Study Coordinator & Contact Info:	CTA/Notice of Grant Award Version & Date:			
Clinical Department:	FDA Documents Received:			
Study Sponsor:	FDA IND/IDE/HDE/HDE number:			
ClinicalTrials.gov number:	Additional documents Received:			
Protocol #:	MAC documents received:			
IRB Identifier:	Patient enrollment status:			
Qualifying Clinical Trial (QCT) Analysis				
The questions below are used to determine if a study meets the NCD qualifying criteria for Medicare Coverage.				
Section I.				

Do ALL three boxes below apply?			DESCRIPTION
1. Medicare Benefit Category Investigation of product/service that is covered by Medicare/Medicaid (e.g., drug, biologic) Note: The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).	**YES** o	**NO** o	
2. Therapeutic Intent Does the study have therapeutic intent stated in the study objective(s), aim(s) or end point(s)?	**YES** o	**NO** o	
3. Diagnosed Disease Does the study enroll subjects with a diagnosed disease, (not healthy volunteers only; controls may be enrolled)?	**YES** o	**NO** o	
Section II. Is the trial "deemed"?			
Do ANY of the following 4 apply?			DESCRIPTION
"Is the study funded by the government? (NIH, CDC, AHRQ, CMS, DOD, VA)"	o		
"Is the study supported by groups funded by the government? (Cooperative groups- NIH, CDC, AHRQ, CMS, DOD, VA)"	o		
Is the study conducted under IND reviewed by the FDA?	o		
Is the study Exempt from IND under 21 CFR 312.2(b)(1)?	o		

"Does the trial meet all of the following desired characteristics? 1. The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes; 2. The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use; 3. The trial does not unjustifiably duplicate existing studies; 4. The trial design is appropriate to answer the research question being asked in the trial; 5. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully; 6. The trial is in compliance with Federal regulations relating to the protection of human subjects; and 7. All aspects of the trial are conducted according to the appropriate standards of scientific integrity."	o		
"IS THIS A QUALIFYING CLINICAL TRIAL? NOTE: ALL CRITERIA FROM SECTION I. MUST BE CHECKED 'YES' & AT LEAST ONE ITEM FROM SECTION II. MUST BE CHECKED TO BE A QCT"	**YES** o	**NO** o	
Research Related Injury and Patient Financial Obligation Language			
Research Related Injury			
The CTA/Informed Consent Form specifies the following parties are responsible for costs due to research related injury:			
Sponsor Paid Items			
The sponsor budget/agreement specifies payment for the following items and services:			
Informed Consent Form Items Promised Free of Charge			
The Informed Consent Form indicates that the patient and/or their insurer will not be billed for the following:			