



Clinical Research Medicare Coverage Analysis

This form should only be completed for those studies attempting to bill study-related protocol items/procedures/ or services to a 3rd party reimbursement group, including Medicare.

Study Identifying Information

TRIAL ID#		Date	
PI Name		Sponsor	
Title			
CTA Status	*	ICF Status	*

Documents for Coverage Analysis

Protocol Version dated:		ICF, IRB approved date:	
Notice of Grant Award:		CT Agreement:	
IND# / IDE#		IND/IDE date	
Comments:			

**Please attach copies of actual IND/IDE letters to this document or upload to the CTMS file online.

Qualifying Clinical Trial Analysis

Requirement	YES	NO	Comment																								
Does the investigational item or service fall into a Medicare benefit category?	<input type="checkbox"/>	<input type="checkbox"/>																									
Does the study have therapeutic intent?	<input type="checkbox"/>	<input type="checkbox"/>																									
Does the study enroll subjects with diagnosed diseases?	<input type="checkbox"/>	<input type="checkbox"/>																									
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Investigational Item / Service Analysis

Analysis Questions	Comments
What is the investigational item or service?	
What is the FDA status of the investigational item or service?	
Does a CMS Benefit Policy, NCD, or LCD allow coverage of the investigational item or service?	

Sponsor Agreement / ICF Review

CTA Review Date:		CTA Status at this review:	*
ICF Review Date:		ICF Status at this review:	*

Review Questions	Yes	No	Comments
The CTA provides for the reimbursement of items and services (**these are not billable to 3 rd party)?	<input type="checkbox"/>	<input type="checkbox"/>	
The CTA provides for payment of complications related services (SAE/AE's)?	<input type="checkbox"/>	<input type="checkbox"/>	Insert language: <input type="text"/>
The CTA subject injury language/compensation matches the ICF compensation language	<input type="checkbox"/>	<input type="checkbox"/>	
The ICF identifies specific services as part of the research protocol to be provided at no cost	<input type="checkbox"/>	<input type="checkbox"/>	

Additional Information / Comments

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Completion Signatures / Dates

Person Completing MCA		Date Completed:	
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