Clinical Trial Billing Coverage Analysis (BCA) Cover Sheet

Drug & Procedure Study Information

Study Title:

Principal Investigator: **Protocol #:**

Sponsor(s):

Protocol Version Date:

Name of Investigational Item or Procedure:

ICF Version Date: **Clinicaltrials.gov #:**

Phase: **BCA Version:**

1. Is the item under investigation for the evaluation of an item or service that falls within a Medicare benefit category (e.g. drugs and biological, inpatient or outpatient services, physician services, diagnostic test)?

If Yes, the category is: - Continue to step 2.

If No **- Stop, trial doesn't qualify**

2. Does the study have therapeutic intent?

If Yes, include statement – Continue to step 3 If No **- Stop, trial doesn't qualify**

Statement(s):

3. Does the study enroll subjects with a diagnosed disease (not health volunteers only)?

If Yes the disease under study is:

If No - Stop, trial doesn't qualify

4. Is the study funded by NIH (or NIH subgroups), CDC, AHRQ, CMS, DOD, or the VA?

If Yes include funding source – **This is a Qualifying Clinical Trial** If No – Go to step 5

Funding Source:

5. Is the study conducted under an investigational new drug (IND) application reviewed by the FDA?

If Yes the IND# is: **This is a Qualifying Clinical Trial** If No – Go to step 6

6. Is the study exempt from having an IND under 21 CFD 312.2(b)(1)?

If Yes – **This is a Qualifying Clinical Trial** If No – Go to step 7

7. If the answers to steps 4, 5, and 6 were all **NO**, then this is **Not a Qualifying Clinical Trial.**

Informed Consent Document

The benefits section of the ICF states:

The cost section of the ICF states:

I, as Principal Investigator, certify that I have reviewed the attached Billing Coverage Analysis along with the Research Finance Compliance Analyst, and have provided my clinical input with regard to standard of care and medical necessity, to the best of my judgment and normal clinical practice guidelines.

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Signature **Date**

I as Research Finance Compliance Analyst, certify that I have reviewed the attached Billing Coverage Analysis along with the Principal Investigator, and confirm to the above to be in compliance with current Medicare regulations and coverage determinations to the best of my knowledge.

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Signature **Date**