Clinical Trial Billing Coverage Analysis (BCA) Cover Sheet

Device Study Information

Study Title:

Protocol #: **Clinicaltrials.gov #:**

Principal Investigator: **Sponsor(s):**

Protocol Version Date: **BCA Version:**

ICF Version Date: **IDE#:**

Name of Investigational Item:

How is the Device Being Supplied? (Circle One): Sponsor (Free of Charge), SLUHN Purchasing

1. Is the device being studied under an investigational device exemption (IDE) category A or B status assigned by the FDA?

If Yes and Category A – Go to step 2 If Yes and Category B – Go to step 3

If No – Go to step 4

2. Is the device intended for use in the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition (i.e., a "stage of disease in which there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment") and has the Medicare Contractor approved the request for the Category A device trial?

If Yes – Go to step 7 If No – **Stop, Routine Costs cannot be billed**

3. Has the Medicare Contractor approved the request for the Category B device trial?

If Yes – Go to step 8 If No – **Stop, Routine Costs cannot be billed**

4. Is device marketed under Humanitarian Device Exemption (HDE)?

If Yes – **Routine costs can be billed** If No – Go to step 5

5. Is device approved by FDA through pre-market approval (PMA) process and being used "on label"?

If Yes – **Routine costs can be billed** If No – Go to step 6

6. Is device cleared by the FDA through the 510(k) process and being used "on label"?

If Yes – **Routine costs can be billed** If No – **Stop, Routine Costs cannot be billed**

7. If a Category A device is used, the routine costs will be covered if the trial is FDA approved and the device is determined to be intended for the use in the diagnosis, monitoring or treatment of an immediately life-threatening disease or condition. The device itself is never covered by Medicare. Medicare Contractor approval is required for Category A trial routine costs coverage.

8. If Category B device is used, the routine costs and possibly the device will be covered if the Medicare contractor approves the study. When determining whether to cover routine costs on a study, the Medicare contractor will consider: 1) medical necessity, 2) if device is appropriate for patient needs, 3) if device is being used in a FDA approved trial, 4) NCD and LCD determinations.

Informed Consent Document

What if any, items and/or services are promised free in the Informed Consent Document? Does the study appear to have therapeutic intent?

The benefits section of the ICF [appears/does not appear] to reflect that the study has therapeutic intent and 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 Financial 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**