

Clinical Trials Coverage Analysis Checklist - Investigational Devices

Trial Title: _____

Sponsor: _____

Sponsor Protocol #: _____

IDE#: _____

Copy of the FDA Approval Letter Present?

_____ Yes

_____ No

(If not, why?) _____

Date Received in Medical Audit:

Protocol _____

Proposed Budget _____

Other _____

Medical Auditor: _____

Forwarded by Medical Audit To/Date:

Name _____

Title/Department _____

Date _____

Name _____

Title/Department _____

Date _____

Is this a Medicare Deemed Qualifying Trial?

_____ Yes

_____ No

Does the Coverage Analysis outcome indicate proceeding with Trial?

_____ Yes

_____ No If no, substantiate here and within each applicable "step" below.

Comments: _____

Step 1: Investigational Device Exemption (IDE)

a. Is the device a Category A device?

_____ Yes Not covered; see NCD 310.1 for guidelines

_____ No (Go to b)

b. Is the device a Category B device?

_____ Yes (Attach copy of FDA approval letter - Go to Step 2)

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No (Note type of device in "Comments" section below, e.g. 510K device. A 510K device is a device that is used for the same purpose as a competitive device, enter 510K number here. Go to Step 2)
510K number: _____

Step Completed **Comments:** _____
 Initials: _____
 Date: _____

Step 2: National Coverage Decision(s)

a. Does a specifically applicable National Coverage Decision (NCD) exist?
 Yes (Attach copy and go to Step 3)
 No (Continue with Step 4)

Step Completed **Comments:** _____
 Initials: _____
 Date: _____

Step 3: National Coverage Decision - Non-Coverage

a. Is the specific NCD a non-coverage decision?
 Yes (The investigational device and procedure are not covered. Go to Step 5)
 No (Go to Step 4)

Step Completed **Comments:** _____
 Initials: _____
 Date: _____

Step 4: Local Coverage Determinations (LCD)

a. Does an applicable LMRP exist?
 Yes (Identify and go to b)
 Identify: _____
 No (Follow specific NCD from Step 3 above, if an NCD exists. Otherwise, go to Step 6)

b. Does the applicable LCD agree with the specific coverage NCD?
 NA (There is no specific coverage NCD or the LCD addresses a separate issue. Go to c)
 Yes (Follow LCD guidelines for analysis. Go to Step 6)
 No (Follow specific coverage NCD. Go to Step 6. *Note: An LMRP cannot withdraw coverage established by an NCD, but it can require additional steps for reimbursement, e.g. prior approval by the Medical Director prior to billing.*)

c. Is the LCD a non-coverage decision?
 Yes (The investigational device and procedure are not covered. Go to Step 5)
 No (Go to Step 6)

Step Completed **Comments:** _____

 Initials: _____
 Date: _____

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Step 5: Care Related to a Non-Covered Investigational Device

_____ **NA** (Go to Step 6)

Care that is related to a non-covered investigational device is also non-covered.

- a. Identify all items and services required in preparation for use of the non-covered device, e.g. preparatory work such as diagnostic labs and other screening procedures.

Identify: _____

- b. Identify all items and services required for implantation or use of the non-covered device, e.g. surgical procedure, monitoring, etc.

Identify: _____

- c. Identify all items and services required following implantation or use of the non-covered device, e.g. x-rays or other diagnostic tests.

Identify: _____

- d. Identify post-discharge / follow-up care that is related to the non-covered device.

Identify: _____

- e. Go to Step 7

Step Completed

Comments: _____

Initials: _____

Date: _____

Step 6: Sponsor Covered Items and Services

Review both the trial budget and contract. Identify items and/or services for which the sponsor is paying. These items and services may not be billed to other third party payers (including Medicare).

Identify: _____

Step 7: Non-covered items or services

Do any gaps exist between non-covered costs **and** what the sponsor is paying for? In other words, are there any services/procedures/items that are not billable and not being paid for by the sponsor?

_____ **Yes** (Identify **each** gap here)

Identify: _____

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_____ No

Step Completed

Comments: _____

Initials: _____

Date: _____

Other comments or outstanding relevant issues or concerns not identified in any "Step" above:

Comments: _____

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If the research budget includes payment for a necessary service also considered routine care -
and the clinical trial sponsor is paying for it - it cannot be billed to Medicare.
In addition, if the sponsor would customarily pay for the service, Medicare will not cover it.
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Coverage Analysis Completed by: _____

Date: _____

1. Forward the original coverage analysis with all attachments to the Contract Manager in the Department of Clinical Research.
2. Retain a complete copy of this checklist and all attachments in the department of Medical Audit. (File by Sponsor name and sponsor protocol number.)

CC: _____
