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| **Clinical Trial Name:****\*\*\* CODING/DOCUMENTATION ALERT- physician documentation must support diagnosis code for patient enrolled in clinical trial (ICD9 - V70.7)** |
| **IRB Approval Date:**  | **Principal Investigator:** |
| **IRB Protocol #** | **Clinical Trial Registry #** | **Department:** |
| **Contact Person:** | **Phone:** | **Contact Email:** |
| **Estimated Start and End Dates:**  | **Estimated Number of Patients:** | **Patient Visits:** |
| [ ]  **Inpatient [ ]  Outpatient**   |  |
|  |
| **Medicare Status (Check one box - #1, #2, #3 or #4):**  | **Coverage Available for:** |
| [ ]  1. **National Coverage Decision** – Any clinical trials receiving Medicare coverage of routine costs must meet all of the following three requirements:[ ]  Yes [ ]  No - Covered Benefit – Is the subject or purpose of the trial the evaluation of an item or service that falls within a Medicare benefit category?[ ]  Yes [ ]  No - Therapeutic Intent - Is the trial designed to test toxicity or disease pathophysiology? Does it have therapeutic intent? and,[ ]  Yes [ ]  No - Diagnosed Disease – Are patients with diagnosed disease enrolled, rather than healthy volunteers? Note: Trials of diagnostic interventions may enroll health patients in order to have a proper control group. | Covered Costs – Routine costs in clinical trials include:* Items or services that are typically provided absent a clinical trial (i.e., conventional care);
* Items or services required solely for the provision of the investigational item or service (i.e., administration of a non-covered chemotherapy agent);
* Items or services that are the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and,
* Items or services needed for reasonable and necessary care arising from the provision of an investigational item or services- in particular, for the diagnosis or treatment of complications.
* Claim must include condition code 30 (qualifying clinical trial) and HCPCS modifier “Q1”-facility outpatient claims
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| **Is the trial (Check one box –A or B):** |  |
| [ ]  A. **Deemed Qualified** – Effective September 19, 2000, a clinical trial can be deemed to be automatically qualified if it meets one of the following four requirements:[ ]  Yes [ ]  No – Is the trial funded by NIH, CDC, AHRQ, HCFA, DOD or VA;[ ]  Yes [ ]  No - Is the trial supported by centers or cooperative groups that are funded by NIH, CDC, AHRQ, HCFA, DOD or VA;[ ]  Yes [ ]  No- Is the trial conducted under an investigational new drug/new device application (IND or IDE) reviewed by the FDA; and [ ]  Yes [ ]  No- Is the trial a drug trial that is exempt from having an IND under 21 CFR 312.2(b)(1) and is deemed automatically qualified until the qualifying criteria are developed and the certification process is in place. | Medicare will cover the routine costs of qualifying drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) and which are deemed automatically qualified until the qualifying criteria are developed and the certification is in place (ref. 310.1 routine costs in Clinical Trials (effective July 9, 2007) Rev. 74Non-Covered Costs* The investigational item or service, itself;
* Items or services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical
* management of the patient (i.e., monthly CT scans for a condition usually requiring only a single scan);
* Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial; and,
* Items and services provided solely to determine study eligibility; and,
* Items and services provided solely to satisfy research study requirements.
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| [ ]  2. B. **Certain Non-Qualifying Studies** – If study does not qualify under National Coverage Decision due to the fact that the purpose of the study is not the evaluation of an item/service within a Medicare Benefit category. | Covered Costs:* Treatment of complication arising from delivery of non-covered items or services; and,
* Reasonable and necessary care unrelated to the study.
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| **INVESTIGATIONAL DEVICE STUDY:****\_\_\_ Yes DEVICE NAME\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Is the device provided free of charge? Yes\_\_\_ No\_\_\_****\_\_\_ NA** | **COVERAGE AVAILABLE FOR:****-items/services provided free of charge by sponsor may not be billed to be paid by Medicare; providers are not required to submit the charge to Medicare. (If reporting is required to receive payment on covered routine services, submit the token charge as non covered)** |
| [ ]  3. **Category A Device** – Considered experimental.   - category assigned by FDA  | Covered Costs:* Routine costs, as described above, involving Category A device when the device is determined to have been used in diagnosis, monitoring, or treatment of an immediately life threatening disease or condition.
* REQUIRES NOTIFICATION TO MAC (attach documentation when Cahaba response received)
* Bill Device charge to Medicare in “NON COVERED” field with Revenue code 0624 and modifier Q0
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| [ ]  4. **Category B Device** – Proven technologies where initial questions of safety and effectiveness have been resolved. Devices in this category represent evolutionary changes in proven technologies. | Covered Costs:* The investigational device, itself (if not provided free of charge by the sponsor)
* REQUIRES NOTIFICATION TO MAC (attach documentation when Cahaba response received)
* IDE Category B device billed under revenue code 0624 and modifier “Q0”
* If device provided free of charge, show device charge in “NON COVERED” column
* All routine costs, as defined above.

Non-Covered Costs:* Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (i.e., monthly CT scans for a condition usually requiring only a single scan);
* Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial;
* Items and services provided solely to determine study eligibility;
* Items and services provided solely to satisfy research study requirements.
 |
| **Submitted by:** | **Date:** |
| **Phone:** | **Email:** |
| **Date Approved by Reviewed by Research Billing Committee:** | **Signature of Approver:** |

REFERENCES:

<http://www.cms.hhs.gov/mcd/search.asp>

NCD for Routine Costs in Clinical Trials (310.1) updated 10-9-2007

<http://www.cms.hhs.gov/Manuals/IOM/list.asp>

 Medicare Claims Processing, 100-04 Medicare Claims Processing Manual

Chapter 32 Billing Requirements for Special Services

Section 68- Investigational Device Exemption and Section 69 Qualifying Clinical Trials

MLN Matters SE0882 9/29/08-Clarification of Medicare Payment for Routine Costs in a Clinical Trial

Medicare Benefit Policy Manual-Chapter 14-Medical Devices

Updated 9-2011/jw