Submitting an Investigational Device to Cahaba GBA for Approval

Cahaba Government Benefit Administrators®, LLC (Cahaba GBA) is responsible for the administration of all Medicare Part A and Part B claims for hospital and physician services in Alabama, Georgia and Tennessee. All IDE Category B and Post Market Approval (PMA) for Carotid Artery Stenting devices must be approved by the Medical Director at Cahaba GBA.

The information below explains Cahaba’s requirements for the submission for approval of a new investigational device and extension of a previously approved IDE. Cahaba requires that only one person per facility may correspond with them regarding IDEs. Judi Campbell (judith.campbell@emoryhealthcare.org) is the “contact person” through whom all requests for approval must be submitted. Once all documents (as outlined below) have been prepared, they should be sent to Judi electronically. She will then review them to ensure that all is in order and send on to Cahaba.

Though this is mentioned below, we want to emphasize the following:

- If the trial extends beyond the end approval date, then we must submit an IRB renewal approval letter to CMS. This needs to be sent to Judi Campbell as well.
- It is important to submit these requests for renewal approval in a timely manner. Cahaba issued a special notice last year about the need for timely submission of renewals, as a delay could mean non-reimbursement of claims.
- It is your responsibility to provide the IRB renewal approval letters to Judi Campbell.
- Any changes to the original submission, including a change in provider(s), should be sent to Cahaba through the designated “contact person” (Judi) as soon as possible.

Investigational Device Submission Requirements

The following submission requirements apply to providers who bill to Cahaba GBA.

IDE Category B and Post Market Approval (PMA) for Carotid Artery Stenting are the only devices requiring contractor notice and approval for billing. Other devices and clinical trials do not require contractor notification. If you have an investigational device and are unsure if it needs to be approved by Cahaba for Medicare billing, please call or e-mail Judi.

For details regarding coverage and billing, please reference the Medicare Benefit Policy Manual, Chapter 14 and the Medicare Claims Processing Manual, Chapter 32, Section 69.

We may combine Part A and Part B requests into a single submission.

When submitting a request, please submit the following information/documentation:

- Completed Investigational Device Cover Form
  (Please note – Judi Campbell completes this form.)

- A signed copy of the “final” FDA approval letter demonstrating device status and approval from the FDA to the participating company or manufacturer.

- A copy of the protocol you intend to follow when performing the procedure utilizing the device.

- A copy of the agreement between the company or manufacturer and the provider, furnishing the details of provider participation in the study.
- Any product literature illustrating the device and/or the procedure.
- A list of any alternative devices, therapies, etc., that may be available to treat the indicated disease.
- A copy of the protocol used for obtaining informed consent from beneficiaries for their participation in the study.
- An institutional review board (IRB) approval letter or a statement from the provider assuring the approval has been obtained from the study institution.

Any changes to the submitted information (including a change in providers) should be submitted as soon as possible to Judi Campbell so that she can submit to Cahaba. Change includes a change to the IRB study approval end date; services beyond this date will be denied.

Once the packet has been approved by the Cahaba Medical Director, an approval letter is e-mailed to the EHC Compliance Office and then distributed to EHC identified staff.

**Renewal**

**Trial Extensions:** If the trial extends beyond the date of the original IRB approval end date, please submit the IRB Extension Notice to Judi Campbell.

Once the renewal packet has been reviewed and approved, Cahaba sends an approval letter to the EHC Compliance Office and they in turn distribute to identified staff.

**Failure to timely submit the renewal may result in denied claims.**

**NOTE:** Please allow a minimum of 7-10 days for processing your application by Emory.