FIRST COAST SERVICE OPTIONS, INC.

WHEN EXPERIENCE COUNTS AND QUALITY MATTERS

Post-market approval (PMA) and 510K studies for carotid artery stenting (CAS)

Please note: These studies are limited to Food and Drug Administration (FDA)-approved carotid artery stents (CAS)

No other post-approval studies should be submitted to the Medicare administrative contractor, First Coast Service Options (First Coast) for approval.

Per the Centers for Medicare & Medicaid Services (CMS) internet-only manual (IOM), Pub. 100-04, to receive reimbursement, providers should submit the following items to the Medicare contractor:

- ☐ The FDA acknowledgment letter, and
- ☐ The CMS letter providing coverage for the extension study to the Medicare contractor.
- ☐ Post-market approval for CAS study number: PXXXXX
- ☐ Post-approval for 510K extension studies: IXXXXX
- ☐ The name of the study and the stent (both trade, common or usual and classification name) and a narrative description of the stent. Include a statement as to the stent similarities and differences from other stents if not explicitly and clearly indicated in submitted documents.
- ☐ Identification of the sponsor of the study and of the funding agency and/or organization if different from the sponsor.
- ☐ Identification of the principle investigator and sub-investigators. Please include a list of all other contact persons (anyone we are allowed to exchange information with regarding the study). Please include phone numbers and e-mail addresses.
- ☐ A copy of the complete FDA approval letter(s) provided to the principle investigator (PI) and/or the sponsor or manufacturer of the carotid stent. Redacted letters and/or letters with blacked out areas are not acceptable. Conditional letters are acceptable if all of the patient safety issues have been addressed. Sending only page one of the FDA letter is not acceptable. Each site requesting a Post-Approval for CAS approval letter must provide the entire FDA letter(s).
- ☐ A copy of the approval letter from the institutional review board (IRB) with the meeting date and the expiration date listed and including the Principle Investigator (PI) and sponsor identifiers.
- ☐ A copy of the complete study protocol, including patient inclusion criteria. Abbreviated summaries of the protocol are not acceptable.
- ☐ A copy of the IRB-approved informed patient consent with PI and sponsor identifiers listed.
- ☐ A copy of the CMS letter providing coverage for the post–market approval or 510K extension study.
- ☐ A copy of the protocol for obtaining informed patient consent.
- ☐ Copies of all agreements between the sponsor and the PI, including but not limited to, complete financial agreements, any and all payments for each aspect of the study with PI and sponsor identifiers listed.

I certify the above is accurate and complete and understand that it is my responsibility to ensure that claims are submitted in compliance with Medicare guidelines.

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Signature of Principle Investigator (PI) or proxy

Consideration for approval of the device will occur within 45 days of receipt of all of the required documentation. Incomplete requests are not acceptable and will not be reviewed.

Please submit this document with all of the above required items via email to: clinicaltrials@fcso.com.

Print Reset

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