noridian
Healthcare Solutions

**FDA Approved Carotid PTA with Stent Post Market Studies and Post Market Extension Studies**
**Pre-Approval Data Submission Request**

Please submit the following *required* information to the Contractor for review:

**Note: The verification and validity of all documentation remains the provider's responsibility, as is the guarantee that Medicare is billed in accordance with Medicare guidelines.**

**Device Number**_____

***Carotid PTA with Stent* Post Market Studies:**

☐ 1. FDA acknowledgement letter with assigned "P" number.

☐ 2. A copy of the Provider's institutional review board (IRB) approval.

☐ 3. A sample of the patient consent form.

☐ 4. The coding that will be used to describe the service, procedure and device, on the claim. (Please consult the AMA for Part B coding advice and the AHA for Part A coding advice.)

***Carotid PTA with Stent* Post Market Extension Studies:**

Submitted the following documentation as well as documents listed above:

☐ 5. The CMS letter providing coverage for the extension study

Consideration for approval of the device will occur *only* after receipt of *each* of the above-completed items.

PLEASE COMPLETE THE FOLLOWING

Provider (Facility) Name & Oscar Number: _____

**Primary Contact Person**
Name & Position_____
Address: _____
Telephone Number: _____
E-mail: _____

PMA form created by NAS This form is not required, however providers may utilize to assist with providing the required documentation for submission.

**Secondary Contact Person**
Name & Position_____
Address: _____
Telephone Number: _____
E-mail: _____

☐ E-mail Notification of Decision

**Or**
☐ Mail Notification of Decision

**Send all requests using the following:**

Electronic submission, all states: iderequests@noridian.com

**Mail (US, UPS or FedEx)**

Noridian Administrative Services, LLC
Attn: PMA Part A
PO Box 6722
900 42nd Street South
Fargo, ND 58103-6722

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