Data Collection for Medicare Beneficiaries Receiving Carotid Artery Stenting with Embolic Protection

A. Background

To encourage responsible and appropriate use of Carotid Artery Stenting (CAS) with embolic protection, CMS issued a Decision Memo for Carotid Artery Stenting on March 17, 2005. As a result, Medicare covers Percutaneous Transluminal Angioplasty (PTA) of the carotid artery concurrent with the placement of an FDA-approved carotid stent with embolic protection for the following:

•Patients who are at high risk for CEA and who also have symptomatic carotid artery stenosis >70 %. Coverage is limited to procedures performed using FDA-approved carotid artery stenting systems and FDA-approved or -cleared (effective December 9, 2009) embolic protection devices. If deployment of the embolic protection device is not technically possible, and not performed, then the procedure is not covered by Medicare (effective December 9, 2009);

•Patients who are at high risk for CEA [Carotid Endarterectomy] and have symptomatic carotid artery stenosis between 50 % and 70 %, in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (Medicare National Coverage Determination (NCD) Manual 310.1), or in accordance with the NCD on carotid artery stenting (CAS) post-approval studies (Medicare NCD Manual 20.7);

•Patients who are at high risk for CEA and have asymptomatic carotid artery stenosis >80 %, in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (Medicare NCD Manual 310.1), or in accordance with the NCD on CAS post- approval studies (Medicare NCD Manual 20.7).

CMS has determined that CAS with embolic protection is reasonable and necessary {§1862 (A)(1)(a) of the Social Security Act} only if performed in facilities that have been determined to be competent in performing the evaluation, procedure and follow-up necessary to ensure optimal patient outcomes. Standards to determine competency include specific physician training standards, facility support requirements and data collection to evaluate outcomes during a required reevaluation. CMS has created a list of minimum standards modeled in part on professional society statements on competency. All facilities must at least meet CMS's standards in order to receive coverage for carotid artery stenting for high risk patients.

B. Justification

1 . Need and Legal Basis

CMS considers coverage for CAS with embolic protection reasonable and necessary {§1862 (A)(1)(a) of the Social Security Act} for patients at high risk for carotid endarterectomy and who also have symptomatic carotid artery stenosis $\geq$ 70% only if performed in facilities that have been determined to be competent in performing the evaluation, procedure and follow-up necessary to ensure optimal patient outcomes. Standards to determine competency will include specific physician training standards, facility support requirements and data collection to evaluate outcomes during a required reevaluation.

2. Information Users

To qualify for payment, facilities must submit a written affidavit to CMS attesting that the facility has met the minimum facility standards as described in the National Coverage Determination (NCD CAG # 0085R). CMS posts and regularly updates an electronic list of all certified facilities viewable at: http://www.cms.hhs.gov/MedicareApprovedFacilitie/CASF/list.asp#TopOfPage. In addition, CMS publishes quarterly updates of the list of approved facilities in the Federal Register. A new affidavit is required every two years to ensure that facilities maintain high standards.

3. Use of Information Technology

The written affidavits to CMS attesting that the facility has met the minimum facility standards were submitted to the agency via mail for all currently CMS approved facilities. These affidavits are not included in the burden calculation. The information is being used to support payment to the facility and provider. The agency has used information technology by making a list of all approved facilities available at the website listed above. The subsequent data collection will utilize electronic data forms which will be exchanged through the CMS website and a CMS email address.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

This collection of information does not impact small businesses or other small entities.

6. Less Frequent Collection

The collection of this data occurs once every two years for each facility that wants certification to perform the procedure on the high risk patient for CEA. If the information is not collected CMS cannot meet its responsibility to encourage responsible and appropriate use of CAS with embolic protection.

7. Special Circumstances

No special circumstances cause the information collection to be conducted in a manner specified in the instructions.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice for this collection published on June 28, 2013.
The NCD was opened on June 18, 2004. During the period between opening and closing the NCD, CMS met with representatives from the device manufacturers and professional provider societies to discuss facility experience requirements, physician training programs, and appropriate patient selection criteria in relation to CAS. CMS convened a town hall meeting

on August 17, 2004 in Baltimore where these issues were discussed and the attendees were representative of the medical device industry, FDA and physician professional societies. The list of minimum standards for facilities was modeled in part on professional society statements on competency.

9. Payments/Gifts to Respondents

No payment or gift will be provided to respondents.

10. Confidentiality

CMS shall be assured that all applicable patient confidentiality, privacy, and other Federal laws are complied with, including the Standards for Privacy of Individually Identifiable Health Information (Privacy Rule).

11. Sensitive Questions

No questions of a sensitive nature are included in this data collection.

12. Burden Estimates (Hours & Wages)

The burden associated with this requirement is the time and effort necessary for the facility to retrieve, organize and submit the data elements, and does not include the written affidavit discussed above. Because each data element requested should already be documented to ensure compliance with the NCD, we have estimated this process to take 30 minutes per facility or 500 hours annually. This estimate accounts for facilities that have not performed any procedures and thus would require no time as well as facilities that have performed a large number of procedures (100+) and would require more time.

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

No annualized cost to the Federal government will be incurred.

15. Changes to Burden

None.

16. Publication/Tabulation Dates

There are no publication or tabulation dates.

17. Expiration Date

CMS would like an exemption from displaying the expiration date as these forms are used on a continuing basis. To include an expiration date would result in having to discard a potentially large number of forms.