Supporting Statement – Part A

Supporting Statement for data collection for Medicare beneficiaries receiving beta amyloid positron emission tomography (PET) for dementia and neurodegenerative disease

A. Background

In the Decision Memorandum #CAG-00431N issued on September 27, 2013, CMS determined there is sufficient evidence that the use of beta amyloid PET is promising in 2 scenarios: (1) to exclude Alzheimer's Disease (AD) in narrowly defined and clinically difficult differential diagnoses; and (2) to enrich clinical trials seeking better treatments or prevention strategies for AD. CMS will cover one beta amyloid PET scan per patient through Coverage with Evidence Development in clinical studies that meet specific criteria established by CMS. Clinical studies must be approved by CMS.

Radioactive tracers used in the scan must be FDA approved. Approved studies must address defined research questions established by CMS. Clinical studies in this National Coverage Determination (NCD) must adhere to the designated timeframe and meet standards establish by CMS in the NCD.

B. Justification

1 . Need and Legal Basis

To qualify for payment, providers must prescribe beta amyloid PET scans for beneficiaries with suspected dementia. The statuary authority for this policy is section 1862 (a)(1)(E) of the Social Security Act. The need to prospectively collect information at the time of the scan is to assist the provider in decision making for patient management.

2. Information Users

To qualify for payment, providers must prescribe beta amyloid PET for beneficiaries with a set of clinical criteria specific to each suspected dementia. Data elements will be transmitted to CMS for evaluation of the short and long-term benefits of beta amyloid PET to beneficiaries and for use in future clinical decision making.

3. Use of Information Technology

One-hundred percent of the collection of this information is through electronic means. The usual CMS forms and means of submission for claims by providers for payment will be

utilized. In addition, to qualify for payment, providers who prescribe beta amyloid PET scans must only do so for beneficiaries with a set of clinical criteria specific to each symptom type.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained by other sources.

5. Small Businesses

This collection of information may impact small businesses or other small entities.

6. Less Frequent Collection

The collection of this data occurs each time a beneficiary undergoes a beta amyloid PET scan. The physician prescribing the technology will need to submit this information each time the patient undergoes a beta amyloid PET. If the information is not collected, CMS cannot meet its responsibility to encourage responsible and appropriate use of beta amyloid PET.

7. Special Circumstances

The respondent (i.e., the provider) is required to report the information to the agency for payment.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on September 25, 2015. There were no comments received.

9. Payments/Gifts to Respondents

No payment or gift will be provided to respondents, other than remuneration for performing the beta amyloid PET scan.

10. Confidentiality

As part of the CMS Coverage with Evidence Development (CED) program, this study is required to comply with all federal privacy and human subject protection rules. In addition, all CED required studies that require data collection to be submitted to CMS are covered under System of Records (see Data Collection Secondary to Coverage Decision (DCSCD) System HHS/CMS/OCSQ, System No. 09-70-0547, 70 FR 53667.

11. Sensitive Questions

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

12. Burden Estimates (Hours & Wages)

We estimate that the total annual burden associated with this requirement is 32,375 hours.

The estimate comes from the following calculation:

- The sample size estimate is 18,500 Medicare beneficiaries over 5 years = 3,700 patients/year
- There will be approximately 300 providers involved = 12.3 patients per provider/year
- The time to complete the forms is estimated to be 1.75 hours per patient (there are 3 forms to be completed per patient per provider at 30 minutes, plus 15 minutes of staff time per patient = 1.75 hours).
- The total amount of time per year for each provider is= 1.75 hours X 12.3 patients = 21.58 hours.
- The total yearly time burden is 21.58 hours X 300 providers = 6,475 hours.
- Over the 5 years of the study, the estimated burden is 5 X 6,475 hours = 32,375 hours.
- The wage burden is estimated to be $195 per patient per physician. This is based on a wage estimate of $125/hr. for physicians and $30/hr. for staff. Based on 12.3 patients/provider/yr., this is an annual expense of $2,399 per provider. Multiplying that by 5 = $11,995 per provider during the life of the study.

13. Capital Costs

There are no capital costs associated with this collection. The software used to complete and transmit the form will be provided free of charge, by downloading the software from the national registry.

14. Cost to Federal Government

There is no annual cost to the Federal government. We estimate that the supervision of this study will require approximately 0.10 FTE/year. That amount equals $13,000.

15. Changes to Burden

This is a new information collection.

16. Publication/Tabulation Dates

There are no publication or tabulation dates.

17. Expiration Date

No exemption from displaying the expiration date is requested.

18. Certification Statement

There are no exemptions to the certification statement.