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# Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease CED Study Registry

All fields marked with an asterisk (*) are required.

***SAMPLE FORM: FOR REFERENCE ONLY***

## General Information

National Provider Identifier (NPI) *

XXXXXXXXXX

Medicare Beneficiary ID (MBI) *

XXXXXXXXXXX

For more information refer to the NPI Registry:
https://npiregistry.cms.hhs.gov/search

Verified

Reset Form

If you need to re-enter your NPI and MBI to begin again, select the Reset button in order to clear those fields and restart your entry.

## CED Study Identifier

NCT*

99999999

## Contact Information

Submitter Address List

1234 ANYSTREET, ANY CITY, ST, 55555-5555

Select an address or manually enter if not listed.

Submitter Email Address*

asample@samplecompany.com

Your email address will be kept confidential and will not be publically shared.

Street Address

1234 ANYSTREET

State*

State

City*

ANY CITY

Zip Code*

55555-5555

## Diagnosis

Clinical Diagnosis*

MCI Due to AD

Mild Cognitive Impairment due to Alzheimer's Disease (MCI due to AD)

Date of Clinical Diagnosis*

06/19/2023

## One of the below tests to confirm amyloid pathology is required

Amyloid PET Scan*

Positive

Date of Amyloid PET Scan*

06/15/2023

CSF Test*

Not Performed

Other Amyloid Test*

Not Performed

Other Information

***SAMPLE FORM: FOR REFERENCE ONLY***

## At least one of the following cognitive tests are required

MoCA Score

26

Date of MoCA

06/14/2023

Other Cognitive Test

## At least one of the following functional tests are required

FAQ Score

7

Date of FAQ

06/14/2023

Other Functional Test

## The test below is optional

Did you perform a CDR?

- ○ Yes
- ◉ No

## Additional Required Information

Is the patient on anticoagulation?*

- ◉ Yes
- ○ No

Is the patient on antiplatelets?*

- ○ Yes
- ◉ No

Monoclonal Antibody Used*

Lecanemab

Is there evidence of significant ARIA-E?*

- ◉ Yes
- ○ No

Date of ARIA-E test*

06/20/2023

Is there evidence of significant ARIA-H?*

- ◉ Yes
- ○ No

Date of ARIA-H test*

06/20/2023

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Submit

# CMS Alzheimer's Disease Registry/Data Collection Dictionary

(As of June 30, 2023)

| Data Element | Description |
|---|---|
| General Information | |
| National Provider Identifier (NPI)* | Entry required. The NPI is a unique 10-digit number used to identify health care providers. All health care providers who are HIPAA-covered entities, whether individuals or organizations, must obtain an NPI. Once assigned, an NPI remains the same, even if the provider has a change of name, address, or other information. An individual clinician can look up their NPI here: https://npiregistry.cms.hhs.gov/search. Results will not be made public at the individual clinician or clinician group level. |
| Medicare Beneficiary ID (MBID)* | Entry required. CMS uses MBIDs as the unique identifier for all Medicare transactions like billing, eligibility status, and claim status. Every person with Medicare has been assigned an MBI. The MBI is confidential like the Social Security Number and will be protected as personally identifiable information by the protocol. |
| CED Study Identifier | |
| NCT* | Entry required. This field will auto-populate with CMS' anti-beta mAbs CED Study identification (NCT) number. As additional approved CED protocols become available, they will be included as options. |
| Contact Information | |
| Submitter Address List | This field will auto-populate based on the information on file with the NPI. If needed, the submitter can update the address fields. |
| Submitter Email Address* | Entry required. CMS requests this to allow for communication with the submitting provider to resolve any questions to expedite coverage determination. This information is considered personally identifiable information and will not be publicly shared. |
| Street Address | This field records the street number and name associated with the submitter's address. |
| State* | Entry required. This field records the two-letter abbreviation or full name of the state associated with the submitter's address. |
| City* | Entry required. This field records the name of the city associated with the submitter's address. |

| Data Element | Description |
|---|---|
| Zip Code* | Entry required. This field records the five-digit zip code associated with the submitter's address. |
| Diagnosis | |
| Clinical Diagnosis* | Entry required. Clinical diagnosis includes mild cognitive impairment (MCI) due to Alzheimer's disease (AD) or mild AD dementia, both with confirmed presence of amyloid beta (Aβ) pathology consistent with AD. The clinical diagnosis will be identified by clinicians using standard-practice, evidence-based guidelines, which involves using cognition and functional assessments combined with evidence of amyloid on imaging and/or other clinically appropriate tests. |
| Date of Clinical Diagnosis* | Entry required. Date of establishing the clinical diagnosis by clinicians should be entered as mm/dd/yyyy. |
| Amyloid PET Scan* | Entry required. CMS defers to clinicians' judgment for determining whether the results of amyloid positron emission tomography (PET) scan was positive or negative. If no amyloid PET scan was performed, the "Not performed" option should be selected. |
| Date of Amyloid PET Scan* | Entry required if amyloid PET scan was performed. Date of amyloid PET Scan should be entered as mm/dd/yyyy. |
| CSF Test Result* | Entry required. CMS defers to clinicians' judgment for determining whether the results of cerebral spinal fluid (CSF) test were positive or negative. If no CSF test was performed, the "Not performed" option should be selected. |
| Date of CSF Test Result* | Entry required if CSF test was performed. Date of CSF test should be entered as mm/dd/yyyy. |
| Other Amyloid Test* | Entry required. This field records the results of any other amyloid test that has been performed. If no other amyloid test was performed, the "Not performed" option should be selected. |
| Date of Other Amyloid Test* | Entry required if another amyloid test has been performed. Date of performing any other amyloid test should be entered as mm/dd/yyyy. |
| Type of Other Amyloid Test* | Entry required if another amyloid test has been performed. Type of any other amyloid test should be specified in this field. |

| Data Element | Description |
|---|---|
| Other Information | Clinicians may feel other diagnostic or clinical information is critical for their evaluation of patients with MCI due to AD or mild AD dementia. Therefore, the data submission portal provides an open text field to enable the person submitting the data to include other relevant information not required by the CED protocol but potentially valuable for assessment of anti-Aβ mAb real-world efficacy. |
| At least one of the cognitive tests below is required. | |
| MoCA© Score | This field records the score of Montreal Cognitive Assessment (MoCA©) test, which ranges from 0 to 30. |
| Date of MoCA© | Date of administering MoCA© test (if administered) should be entered as mm/dd/yyyy. |
| Other Cognitive Test | This field records the name of any other cognitive test that has been performed. Example: "Mini-Mental State Exam" with a score of 26. |
| Other Cognitive Test Score | Entry required if another cognitive test has been performed. Score of other cognitive test should be entered. |
| Date of Other Cognitive Test | Entry required if another cognitive test has been performed. Date of the other cognitive test should be entered as mm/dd/yyyy. |
| At least one of the functional tests below is required. | |
| FAQ Score | This field records the score of Functional Activities Questionnaire (FAQ), which ranges from 0 to 30. |
| Date of FAQ | Date of administering FAQ (if administered) should be entered as mm/dd/yyyy. |
| Other Functional Test | This field records the name of any other functional test that has been performed. |
| Other Functional Test Score | Entry required if another functional test has been performed. Score of the other functional test should be entered. |
| Date of Other Functional Test | Entry required if another functional test has been performed. Date of the other functional test should be entered as mm/dd/yyyy. |
| This test is optional. | |
| Did you perform a CDR? | The Clinical Dementia Rating (CDR) is an optional test. This field records whether a CDR has been performed. |

| Data Element | Description |
|---|---|
| Memory* | Entry required if CDR was performed. This field records the score of "Memory" domain of CDR, ranging from 0 to 3. |
| Orientation* | Entry required if CDR was performed. This field records the score of "Orientation" domain of CDR, ranging from 0 to 3. |
| Judgment and Problem Solving* | Entry required if CDR was performed. This field records the score of "Judgment and Problem Solving" domain of CDR, ranging from 0 to 3. |
| Community Affairs* | Entry required if CDR was performed. This field records the score of "Community Affairs" domain of CDR, ranging from 0 to 3. |
| Home and Hobbies* | Entry required if CDR was performed. This field records the score of "Home and Hobbies" domain of CDR, ranging from 0 to 3. |
| Personal Care* | Entry required if CDR was performed. This field records the score of "Personal care" domain of CDR, ranging from 0 to 3. |
| Some of Boxes* | Entry required if CDR was performed. This field will auto-populate based on the scores in the previous six fields (Memory, Orientation, Judgment and Problem Solving, Community Affairs, Home and Hobbies, and Personal Care). |
| Global * | Entry required if CDR was performed. This field records the CDR global score, ranging from 0 to 3. |
| Date for CDR* | Entry required if CDR was performed. Date of administering CDR should be entered as mm/dd/yyyy. |
| Additional Required Information | |
| Is the patient on anticoagulation?* | Entry required. In addition to performing the required cognition and function assessments, prescribing clinicians need to report on the patient's use of anticoagulation therapy. According to patient's medication use, "Yes" or "No" should be selected. |
| Is the patient on antiplatelets?* | Entry required. In addition to performing the required cognition and function assessments, prescribing clinicians need to report on the patient's use of anti-platelet therapy. According to patient's medication use, "Yes" or "No" should be selected. |
| Monoclonal Antibody Used* | Entry required. The generic name of monoclonal antibody (e.g., Aducanumab, Lecanemab) should be specified in this field. |

| Data Element | Description |
|---|---|
| Is there evidence of significant ARIA-E?* | Entry required. CMS defers to clinician's judgment to determine whether evidence of significant amyloid related imaging abnormalities with edema (ARIA-E) was observed. Based on clinician's judgment, either "Yes" or "No" should be selected. |
| Is there evidence of significant ARIA-H?* | Entry required. CMS defers to clinician's judgment to determine whether evidence of significant amyloid related imaging abnormalities with hemorrhage (ARIA-H) was observed. Based on clinician's judgment, either "Yes" or "No" should be selected. |