



Medicare Billing - Coverage with Evidence Development (CED)

August 2024

ALZ-NET CED Approval

The Alzheimer's Network for Treatment and Diagnostics (ALZ-NET) is approved by the Centers for Medicare and Medicaid Services (CMS) as a Coverage with Evidence Development (CED) study and can be used as **a pathway to Medicare coverage for anti-amyloid Alzheimer's therapies that have received traditional FDA approval.**

Study Title	<i>Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease Following Appropriate Use Recommendations in a Medicare Population: A Coverage with Evidence Development Study</i>
ClinicalTrials.gov Number	NCT06170268
CMS Approval Date	29 January 2024

[Link to CMS website authorizing ALZ-NET's Coverage with Evidence Development approval](#)

Coverage under CED Approval

Insurance coverage can only be received for patients that are:

1. Enrolled into the ALZ-NET Protocol by and active ALZ-NET site
2. A Medicare beneficiary with primary insurance of Medicare Part B (traditional Medicare) or Part C (Medicare Advantage plan). Dual-eligible Medicaid coverage is allowed.
3. Being treated with a beta-amyloid targeting monoclonal antibody that has received traditional FDA approval for the treatment of Alzheimer's disease. This includes:
 - LEQEMBI (Lecanemab)
 - KISUNLA (Donanemab)

Coverage under CED Approval

Registration into ALZ-NET must occur **prior to** a patient receiving coverage for an approved therapy.

ALZ-NET Registration confirmation emails should be maintained as documentation in the event that CMS opts to audit the service provider.

Registration confirmation emails should also be provided to the service provider as proof of enrollment. The service provider is the entity administering the treatment and submitting the claim.

[Link to additional Medicare billing information and resources](#)

- Example claim forms
- Medicare Advantage coverage letter template
- Claim denial checklist
- Referral letter to service provider

Billing for LEQEMBI (lecanemab)

Information to include on submitted claim forms:

- HCPCS code: **Leqembi J0174** (Injection, lecanemab-irmb, 1mg)
- Registry Trial number: **NCT06170268**
- One of these modifiers:
 - **Q0** (Investigational clinical service provided in a clinical research study that is in an approved clinical research study), or
 - **Q1** (Routine clinical service provided in a clinical research study that is in an approved clinical research study)
- Diagnosis Codes: **Z00.6** (noting a registry) **AND** one of the following dx codes:
 - G30.0 Alzheimer's disease w/early onset
 - G30.1 Alzheimer's disease w/late onset
 - G30.8 Other Alzheimer's disease
 - G30.9 Alzheimer's disease, unspecified
 - G31.84 mild cognitive impairment, so stated
- Institutional Claims:
 - Type of Bill: 12X, 13X, or 85X
 - Revenue Code: 0636
 - Condition Code: 30

This information should be sent to the billing team of the service provider that administers the treatment to the patient.

Billing for KISUNLA (donanemab)

Information to include on submitted claim forms:

- HCPCS code: **Kisunla J0175** (Injection, donanemab-azbt, 2mg)
- Registry Trial number: **NCT06170268**
- One of these modifiers:
 - **Q0** (Investigational clinical service provided in a clinical research study that is in an approved clinical research study), or
 - **Q1** (Routine clinical service provided in a clinical research study that is in an approved clinical research study)
- Diagnosis Codes: **Z00.6** (noting a registry) **AND** one of the following dx codes:
 - G30.0 Alzheimer's disease w/early onset
 - G30.1 Alzheimer's disease w/late onset
 - G30.8 Other Alzheimer's disease
 - G30.9 Alzheimer's disease, unspecified
 - G31.84 mild cognitive impairment, so stated
- Institutional Claims:
 - Type of Bill: 12X, 13X, or 85X
 - Revenue Code: 0636
 - Condition Code: 30

This information should be sent to the billing team of the service provider that administers the treatment to the patient.

Medicare Payment

Sites will get the usual Medicare payment and cost-sharing to administer the applicable treatments under CED. Patients, or their applicable secondary insurance, will be charged the standard 20% coinsurance of the Medicare-approved amount for the medication after they meet the Part B deductible. Read about how [Original Medicare pays for Part B biologics and drugs.](#)

Medicare pays for some separately payable Medicare Part B-covered drugs and biologics (including LEQEMBI™) using the average sales price (ASP) methodology. Medicare pays most separately payable drugs and biologics at a rate of ASP plus 6%. To calculate the ASP and payment of each drug and biologic, manufacturers submit sales data, including discounts. CMS publishes the payment amounts each quarter.

Can a site participate in multiple CED registries?

Yes, a site can participate in ALZ-NET in addition to other CMS-approved CED studies (i.e. the CMS National Patient Registry). However, a site and patient only needs to participate in one CMS-approved study to get Medicare payment for the treatment.

If a patient is enrolled in one registry but wants to switch to ALZ-NET, the site must ensure proper registration into ALZ-NET and that the NCT coding is updated on the claim submission form.