

CMS National Patient Registry for New Alzheimer's Drugs

Things to know for clinicians

Medicare now covers Leqembi more broadly

On April 7, 2022, CMS issued a National Coverage Determination ([NCD](#)) that covers monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease approved by the Food and Drug Administration (FDA). As of July 6, 2023, Medicare more broadly covers Leqembi (lecanemab-irmb) under this NCD. The FDA gave traditional approval for Leqembi for treatment in July 2023.

Medicare covers the drugs with traditional FDA approval in this class when a prescribing clinician or their staff decides the Medicare coverage criteria is met and also submits information to help answer treatment questions in a qualifying study. **You can participate in the CMS National Patient Registry (or another CMS-approved study) to get Medicare payment for treating your patients with Leqembi.**

Using the free CMS National Patient Registry

Registries are common tools in clinical settings to successfully gather information on patient outcomes. CMS carefully balanced the need to collect information while keeping the CMS National Patient Registry as easy to use as possible.

There's no fee to use the simple [CMS National Patient Registry](#), and you can fill it out using information from your patient's medical records. You can also review an example of a completed registry form or watch a video of someone completing the registry form [here](#).

Submitting data to the CMS National Patient Registry

As a prescribing clinician, you or your staff submit data at initial (baseline) treatment using the CMS data submission portal (the CMS National Patient Registry). After the initial data submission, data is submitted every six months for up to 24 months (five total assessments).

Questions about the CMS National Patient Registry?

Available 24 hours Monday-Sunday:

- Submit a service ticket:
https://cmsqualitysupport.servicenowservices.com/ccsq_support_central
- Email us: qnetsupport@cms.hhs.gov

Call us Monday - Friday from 7 AM - 7 PM CT:

- Phone: (866) 288-8912
- TTY: 711

Can I participate in multiple registries?

Yes, you can participate in other registries or CMS-approved studies in addition to the CMS National Patient Registry. Other registries may become available in the coming months and will be posted on the CMS website. You only have to participate in one CMS-approved study to get Medicare payment for this treatment. Find a list of all other [CMS -approved studies for the NCD here](#).

Medicare payment

You'll get the usual Medicare payment and cost-sharing to administer Leqembi. Your patients with Original Medicare will pay 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](#).

Billing Medicare for Leqembi

For dates of service beginning July 6, 2023, Medicare will pay for Leqembi (lecanemab-irmb) when you submit a valid claim and information to help answer treatment questions in a qualifying study.

Medicare is implementing a new HCPCS code for Leqembi on a very compressed schedule to allow you to submit claims as soon as possible. **Submit claims on or after July 25, 2023.**

Include the following on your claim:

- For dates of service beginning July 6, 2023, **use HCPCS code: Leqembi J0174** (Injection, lecanemab-irmb, 1mg)
- Registry trial number (8-digit number) [Use "99999999" temporarily until a permanent-trial number is assigned]
- 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