LEQEMBI®
(lecanemab-irmb) 100 mg/mL
INJECTION FOR INTRAVENOUS USE

Coding for LEQEMBI® for Intravenous Use

Please refer to the tables below for examples of codes that may be appropriate for LEQEMBI. This document is for informational purposes only and does not reflect a comprehensive list of codes. Correct coding and compliance with all applicable payer requirements is the responsibility of the provider submitting a claim for the item or service. Please see FDA-approved indication for LEQEMBI and check with the payer to verify coding or special billing requirements. Other codes may be appropriate. For questions related to LEQEMBI payer coverage, coding, or billing, contact your local Access and Reimbursement Manager or Eisai Patient Support (EPS).

INDICATION

LEQEMBI® [(lecanemab-irmb) 100 mg/mL injection for intravenous use] is indicated for the treatment of Alzheimer's disease (AD). Treatment with LEQEMBI should be initiated in patients with mild cognitive impairment (MCI) or mild dementia stage of disease, the population in which treatment was initiated in clinical trials.

IMPORTANT SAFETY INFORMATION

WARNING: AMYLOID-RELATED IMAGING ABNORMALITIES (ARIA)

- **Monoclonal antibodies directed against aggregated forms of beta amyloid, including LEQEMBI, can cause ARIA, characterized as ARIA with edema (ARIA-E) and ARIA with hemosiderin deposition (ARIA-H). Incidence and timing of ARIA vary among treatments. ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events, including seizure and status epilepticus, can occur. ARIA can be fatal. Serious intracerebral hemorrhages (ICH) >1 cm, some of which have been fatal, have been observed with this class of medications. Because ARIA-E can cause focal neurologic deficits that can mimic an ischemic stroke, consider whether such symptoms could be due to ARIA-E before giving thrombolytic therapy to a patient being treated with LEQEMBI.**
  - **Apolipoprotein E ε4 (ApoE ε4) Homozygotes: Patients who are ApoE ε4 homozygotes (~15% of patients with AD) treated with this class of medications have a higher incidence of ARIA, including symptomatic, serious, and severe radiographic ARIA, compared to heterozygotes and noncarriers. Testing for ApoE ε4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA. Prior to testing, prescribers should discuss with patients the risk of ARIA across genotypes and the implications of genetic testing results. Prescribers should inform patients that if genotype testing is not performed, they can still be treated with LEQEMBI; however, it cannot be determined if they are ApoE ε4 homozygotes and at higher risk for ARIA.**
- **Consider the benefit of LEQEMBI for the treatment of AD and the potential risk of serious ARIA events when deciding to initiate treatment with LEQEMBI.**

CONTRAINDICATION

Contraindication in patients with serious hypersensitivity to lecanemab-irmb or to any of the excipients. Reactions have included angioedema and anaphylaxis.

RECOMMENDED DOSAGE

The recommended initial dosage of LEQEMBI is 10 mg/kg once every 2 weeks. After 18 months, continue the regimen of 10 mg/kg once every 2 weeks or consider transition to maintenance dosing regimen. The recommended maintenance dose of LEQEMBI is 10 mg/kg once every 4 weeks. LEQEMBI must be diluted then administered as an IV infusion over approximately 1 hour. If an infusion is missed, administer the next dose as soon as possible.

HCPCS codes and 11-digit NDC

HCPCS codes are 5-digit alphanumeric codes that are assigned to drugs by the Centers for Medicare and Medicaid Services (CMS). LEQEMBI has been assigned a unique HCPCS code in the "J" series (known as J codes) effective July 6, 2023: J0174.

Code*	Description
J0174	Injection, lecanemab-irmb, Unit of Service = 1 mg
62856-0215-01†	LEQEMBI supplied in 500 mg/5 mL (100 mg/mL), single-dose vial, white flip cap
62856-0212-01†	LEQEMBI supplied in 200 mg/2 mL (100 mg/mL), single-dose vial, dark grey flip cap

Medicare requires that providers identify any unused portion of a single-dose container by reporting the unused amount with the JW or JZ modifier. Check with other payers to determine if they have similar requirements.

Please see Select Safety Information continued on pages 5-6 and accompanying full Prescribing Information, including Boxed WARNING.

Hospital outpatient revenue codes for IV only

Code	Description
0636	Drug requiring detailed coding
0262	Intravenous therapy/pharmacy services

CPT code for drug administration service for IV only

Code	Description
96365	Intravenous infusion for therapy, prophylaxis, or diagnosis (specific substance or drug), initial, up to 1 hour
96366	Each additional hour
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug (includes highly complex biologic agent administration; e.g., monoclonal antibody agents)
96415	Each additional hour

Example ICD-10-CM diagnosis codes

It is the provider's responsibility to choose the ICD-10 diagnosis code that most accurately describes the patient's diagnoses. Below are representative ICD-10 diagnosis codes that may be relevant to LEQEMBI. Other codes may be appropriate.

Alzheimer's disease

Code	Description
G30.0	Alzheimer's disease with early onset
G30.1	Alzheimer's disease with late onset
G30.8	Other Alzheimer's disease
G30.9	Alzheimer's disease, unspecified[§]

Mild cognitive impairment

Code	Description
G31.84	Mild cognitive impairment of uncertain or unknown etiology[‡]

Eisai cannot guarantee payment of any claim. Coding, coverage, and reimbursement may vary significantly by payer, plan, patient, and setting of care. Actual coverage and reimbursement decisions are made by individual payers following the receipt of claims. For additional information, customers should consult with their payers for all relevant coding, reimbursement, and coverage requirements. It is the sole responsibility of the provider to select the proper code and ensure the accuracy of all claims used in seeking reimbursement. All services must be medically appropriate and properly supported in the patient medical record.

For support with payer-specific LEQEMBI questions or assistance verifying insurance benefits for a specific patient, please contact Eisai Patient Support by visiting EisaiPatientSupport.com/LEQEMBI, or by phone at 1-833-453-7362, or fax at 1-833-770-7017.

Please see Select Safety Information continued on pages 5-6 and accompanying full Prescribing Information, including Boxed WARNING.

Billing Medicare for LEQEMBI for IV only

CMS has provided the following guidance on billing Medicare for LEQEMBI. For dates of service beginning July 6, 2023, Medicare may cover LEQEMBI when a provider submits a valid claim and information to help answer treatment questions in the CMS National Patient Registry or another CMS-approved study. CMS guidance indicates to include the following on the claim:

- Consistent with procedures under Medicare Fee-for-Service, Medicare Advantage plans must collect the applicable registry trial number on each claim or encounter for monoclonal antibodies that receive traditional approval from the FDA. In addition, some Medicare Advantage plans may have specific registry coding requirements that could differ from Original Medicare. Please confirm with the plan sponsor[1]
- Use HCPCS code J0174 (Injection, lecanemab-irmb, 1 mg)
- The CMS Registry trial number (8-digit number): the Permanent Clinical Trial Number is "06058234". Some plans may still be utilizing the temporary Clinical Trial Number, which is "99999999". Please confirm with the plan sponsor. Note: Other CMS-approved registries will have their own unique Permanent Clinical Trial Number for patients participating in those registries, and that Clinical Trial Number should be captured on claims, if applicable
- One of these modifiers:
  - Q0: Investigational clinical service provided in a clinical research study that is in an approved clinical research study
  - 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 diagnosis codes listed in the CMS guidance
- Additional Institutional Claims instruction:
  - Type of bill: 12X, 13X, or 85X
  - Revenue code: 0636
  - Condition code: 30

From CMS National Patient Registry for New Alzheimer's Drugs: Things to know for clinicians, 7/2/2024 and CMS Memo, 8/17/2023.

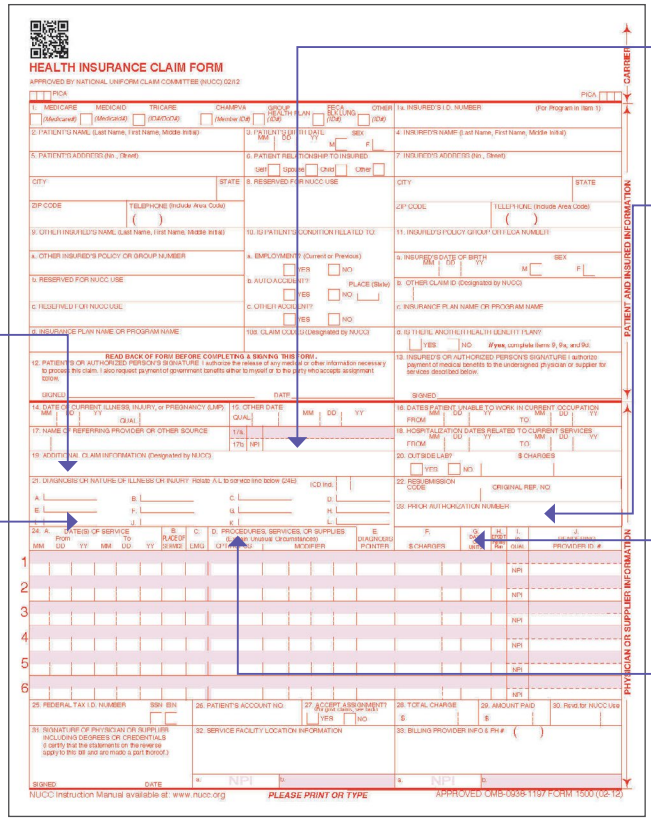
Please visit **https://qualitynet.cms.gov/alzheimers-ced-registry** for additional information and updates.

CMS 1500 (837P)

It is the provider's responsibility to accurately complete CMS Form 1500. The steps below are suggestions only. Specific codes that are appropriate will have to be determined on a case-by-case basis and in consultation with the payer. Other codes may be appropriate. In addition, some Medicare Advantage plan sponsors may have specific billing guidance that could differ from Original Medicare.

FIELD 19 (Loop 2300):
For Medicare Fee-for-Service patients, include the study number. For paper claims, "CT" should precede the 8-digit study number. "CT" is not reported on electronic claims. Place the Clinical Trial Number in the appropriate loop and segment per the MAC

FIELD 21 (Loop 2300):
Enter the most medically appropriate primary/secondary diagnosis codes. For Original Medicare registry enrollees, report appropriate ICD-10 code Z00.6 in the primary or secondary position per CMS or local MAC billing guidelines



FIELD 17B:
Indicate the appropriate NPI number

FIELD 23 (Loop 2300):
If required, provide the prior authorization approval reference number

FIELD 24G (Loop 2400):
Report the number of applicable HCPCS or CPT code units

FIELD 24D (Loop 2400):
Enter the appropriate HCPCS code or the appropriate CPT code for the administration of the product. Relevant modifiers may apply, based on factors listed above. For Medicare registry enrollees, report HCPCS modifier Q0 or Q1 as appropriate

Please see Select Safety Information continued on pages 5-6 and accompanying full Prescribing Information, including Boxed WARNING.

CMS 1450/UB-04 (837I)

It is the provider's responsibility to accurately complete CMS Form 1450/UB-04. The steps below are suggestions only. Specific codes that are appropriate will have to be determined on a case-by-case basis and in consultation with the payer. Other codes may be appropriate. In addition, some Medicare Advantage plan sponsors may have specific billing guidance that could differ from Original Medicare.

FIELD 44 (Loop 2400):

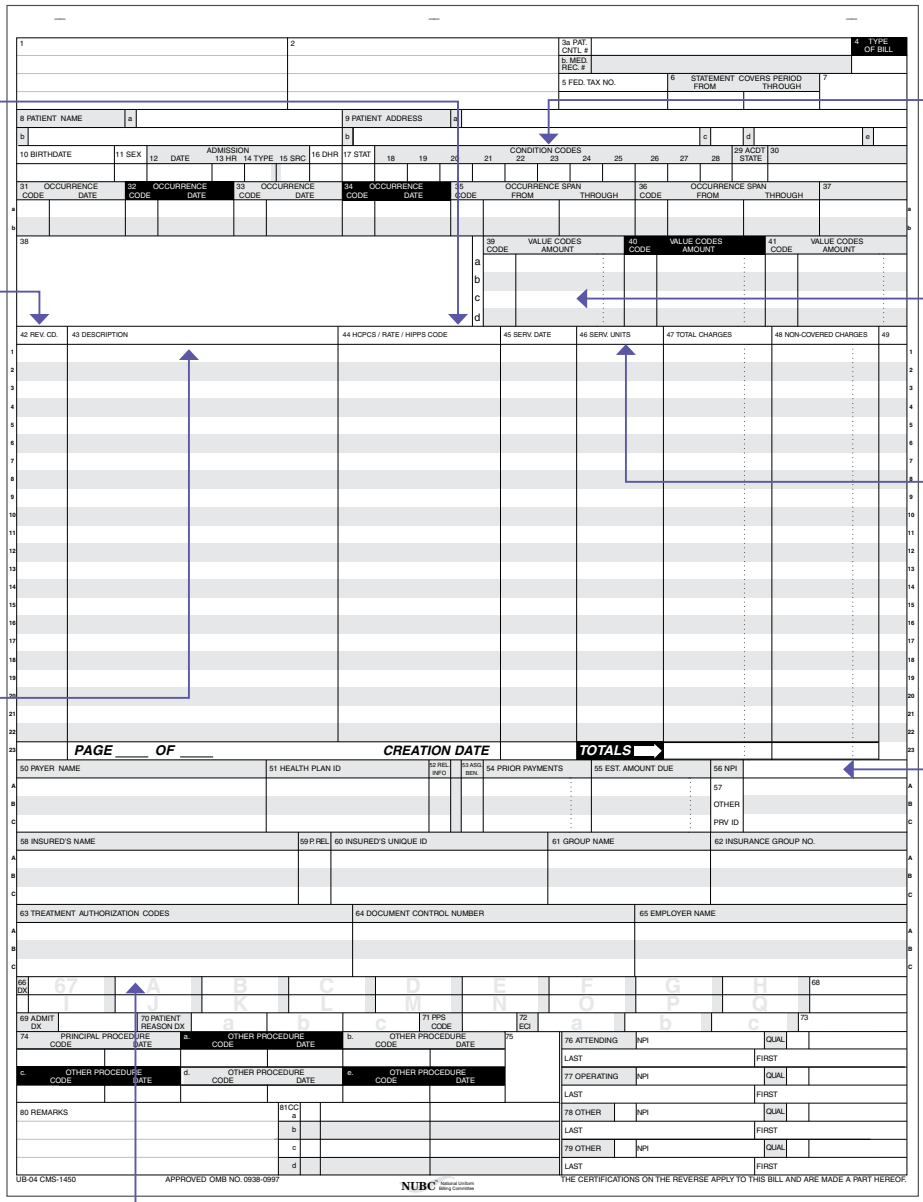
Enter the appropriate HCPCS codes, CPT codes, and modifiers if applicable (modifiers directly follow the code without a space). For Medicare registry enrollees, report HCPCS modifiers Q0 or Q1 as appropriate

FIELD 42 (Loop 2400):

Enter the appropriate revenue code corresponding to the HCPCS or CPT code for field 44 (eg, for LEQEMBI, the appropriate revenue code may be 0636 for drugs and biologicals that require specific identification as required by the payer)

FIELD 43 (Loop 2400):

Provide a brief description that corresponds to the revenue code in field 42 and the product or service in field 44



FIELDS 18-28:

Provide the appropriate condition code. For Medicare Registry Enrollees, report Condition Code 30

FIELD 39:

To report the 8-digit clinical trial number for Medicare Registry enrollees, institutional providers shall code value code 'D4,' where the value code amount equals the 8-digit clinical trial number

FIELD 46 (Loop 2400):

Provide the appropriate units for the HCPCS or CPT code in field 44

FIELD 56 (Loop 2010AA):

Indicate the appropriate NPI number

FIELD 67 (Loop 2300):

Enter the most medically appropriate primary/secondary diagnosis codes. For Original Medicare registry enrollees, report appropriate ICD-10 code Z00.6 in the primary or secondary position per CMS or local MAC billing guidelines

Please see Select Safety Information continued on pages 5-6 and accompanying full Prescribing Information, including Boxed WARNING.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

AMYLOID-RELATED IMAGING ABNORMALITIES

Medications in this class, including LEQEMBI, can cause ARIA-E, which can be observed on MRI as brain edema or sulcal effusions, and ARIA-H, which includes microhemorrhage and superficial siderosis. ARIA can occur spontaneously in patients with AD, particularly in patients with MRI findings suggestive of cerebral amyloid angiopathy (CAA), such as pretreatment microhemorrhage or superficial siderosis. ARIA-H generally occurs with ARIA-E. Reported ARIA symptoms may include headache, confusion, visual changes, dizziness, nausea, and gait difficulty. Focal neurologic deficits may also occur. Symptoms usually resolve over time.

Incidence of ARIA

Symptomatic ARIA occurred in 3% and serious ARIA symptoms in 0.7% with LEQEMBI. Clinical ARIA symptoms resolved in 79% of patients during the period of observation. ARIA, including asymptomatic radiographic events, was observed: LEQEMBI, 21%; placebo, 9%. ARIA-E was observed: LEQEMBI, 13%; placebo, 2%. ARIA-H was observed: LEQEMBI, 17%; placebo, 9%. No increase in isolated ARIA-H was observed for LEQEMBI vs placebo.

Incidence of ICH

ICH >1 cm in diameter was reported in 0.7% with LEQEMBI vs 0.1% with placebo. Fatal events of ICH in patients taking LEQEMBI have been observed.

Risk Factors of ARIA and ICH

ApoE ε4 Carrier Status

Of the patients taking LEQEMBI, 16% were ApoE ε4 homozygotes, 53% were heterozygotes, and 31% were noncarriers. With LEQEMBI, ARIA was higher in ApoE ε4 homozygotes (LEQEMBI: 45%; placebo: 22%) than in heterozygotes (LEQEMBI: 19%; placebo: 9%) and noncarriers (LEQEMBI: 13%; placebo: 4%). Symptomatic ARIA-E occurred in 9% of ApoE ε4 homozygotes vs 2% of heterozygotes and 1% of noncarriers. Serious ARIA events occurred in 3% of ApoE ε4 homozygotes and in ~1% of heterozygotes and noncarriers. The recommendations on management of ARIA do not differ between ApoE ε4 carriers and noncarriers.

Radiographic Findings of CAA

Neuroimaging findings that may indicate CAA include evidence of prior ICH, cerebral microhemorrhage, and cortical superficial siderosis. CAA has an increased risk for ICH. The presence of an ApoE ε4 allele is also associated with CAA.

The baseline presence of at least 2 microhemorrhages or the presence of at least 1 area of superficial siderosis on MRI, which may be suggestive of CAA, have been identified as risk factors for ARIA. Patients were excluded from Clarity AD for the presence of >4 microhemorrhages and additional findings suggestive of CAA (prior cerebral hemorrhage >1 cm in greatest diameter, superficial siderosis, vasogenic edema) or other lesions (aneurysm, vascular malformation) that could potentially increase the risk of ICH.

Concomitant Antithrombotic or Thrombolytic Medication

In Clarity AD, baseline use of antithrombotic medication (aspirin, other antiplatelets, or anticoagulants) was allowed if the patient was on a stable dose. Most exposures were to aspirin. Antithrombotic medications did not increase the risk of ARIA with LEQEMBI. The incidence of ICH: 0.9% in patients taking LEQEMBI with a concomitant antithrombotic medication vs 0.6% with no antithrombotic and 2.5% in patients taking LEQEMBI with an anticoagulant alone or with antiplatelet medication such as aspirin vs none in patients receiving placebo.

Fatal cerebral hemorrhage has occurred in 1 patient taking an anti-amyloid monoclonal antibody in the setting of focal neurologic symptoms of ARIA and the use of a thrombolytic agent.

Additional caution should be exercised when considering the administration of antithrombotics or a thrombolytic agent (e.g., tissue plasminogen activator) to a patient already being treated with LEQEMBI. Because ARIA-E can cause focal neurologic deficits that can mimic an ischemic stroke, treating clinicians should consider whether such symptoms could be due to ARIA-E before giving thrombolytic therapy in a patient being treated with LEQEMBI.

Caution should be exercised when considering the use of LEQEMBI in patients with factors that indicate an increased risk for ICH and, in particular, patients who need to be on anticoagulant therapy or patients with findings on MRI that are suggestive of CAA.

Please see Select Safety Information continued on page 6 and accompanying full Prescribing Information, including Boxed WARNING.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

AMYLOID-RELATED IMAGING ABNORMALITIES (cont'd)

Radiographic Severity With LEQEMBI

Most ARIA-E radiographic events occurred within the first 7 doses, although ARIA can occur at any time, and patients can have >1 episode. Maximum radiographic severity of ARIA-E with LEQEMBI was mild in 4%, moderate in 7%, and severe in 1% of patients. Resolution on MRI occurred in 52% of ARIA-E patients by 12 weeks, 81% by 17 weeks, and 100% overall after detection. Maximum radiographic severity of ARIA-H microhemorrhage with LEQEMBI was mild in 9%, moderate in 2%, and severe in 3% of patients; superficial siderosis was mild in 4%, moderate in 1%, and severe in 0.4% of patients. With LEQEMBI, the rate of severe radiographic ARIA-E was highest in ApoE ε4 homozygotes (5%) vs heterozygotes (0.4%) or noncarriers (0%). With LEQEMBI, the rate of severe radiographic ARIA-H was highest in ApoE ε4 homozygotes (13.5%) vs heterozygotes (2.1%) or noncarriers (1.1%).

Monitoring and Dose Management Guidelines

Baseline brain MRI and periodic monitoring with MRI are recommended. Enhanced clinical vigilance for ARIA is recommended during the first 14 weeks of treatment. Depending on ARIA-E and ARIA-H clinical symptoms and radiographic severity, use clinical judgment when considering whether to continue dosing or to temporarily or permanently discontinue LEQEMBI. If a patient experiences ARIA symptoms, clinical evaluation should be performed, including MRI if indicated. If ARIA is observed on MRI, careful clinical evaluation should be performed prior to continuing treatment.

HYPERSENSITIVITY REACTIONS

Hypersensitivity reactions, including angioedema, bronchospasm, and anaphylaxis, have occurred with LEQEMBI. Promptly discontinue the infusion upon the first observation of any signs or symptoms consistent with a hypersensitivity reaction and initiate appropriate therapy.

INFUSION-RELATED REACTIONS (IRRs)

IRRs were observed—LEQEMBI: 26%; placebo: 7%—and most cases with LEQEMBI (75%) occurred with the first infusion. IRRs were mostly mild (69%) or moderate (28%). Symptoms included fever and flu-like symptoms (chills, generalized aches, feeling shaky, and joint pain), nausea, vomiting, hypotension, hypertension, and oxygen desaturation.

IRRs can occur during or after the completion of infusion. In the event of an IRR, the infusion rate may be reduced or discontinued, and appropriate therapy initiated as clinically indicated. Consider prophylactic treatment prior to future infusions with antihistamines, acetaminophen, nonsteroidal anti-inflammatory drugs, or corticosteroids.

ADVERSE REACTIONS

The most common adverse reactions reported in ≥5% with LEQEMBI infusion every 2 weeks and ≥2% higher than placebo were IRRs (LEQEMBI: 26%; placebo: 7%), ARIA-H (LEQEMBI: 14%; placebo: 8%), ARIA-E (LEQEMBI: 13%; placebo: 2%), headache (LEQEMBI: 11%; placebo: 8%), superficial siderosis of central nervous system (LEQEMBI: 6%; placebo: 3%), rash (LEQEMBI: 6%; placebo: 4%), and nausea/vomiting (LEQEMBI: 6%; placebo: 4%).

Please see accompanying full Prescribing Information, including Boxed WARNING.

*Claims with an unclassified HCPCS code should include additional information about the drug in the ASC X12N 837I claim format in specific locations, or in the "Remarks" section of the CMS-1450 claim form. Medicare hospital outpatient claims with C9399 must include the NDC, the quantity of the drug that was administered (expressed in the unit of measure applicable to the drug or biological), and the date the drug was furnished to the beneficiary (source: Centers for Medicare and Medicaid Services. Claims Processing Manual Chapter 17, Section 90.3). For other unclassified HCPCS codes—including J3490, J3590, and J9999—the additional information may vary by payer but often includes the product name, 11-digit NDC, and quantity administered. Providers should contact their local commercial payers and Medicaid plans for specific information on reporting drugs using unclassified HCPCS codes.

†Format may vary by payer. Verify with payer prior to submitting a claim.

‡Please Note: Some payers may require a secondary code to describe the etiology of the diagnosis. In that case, one of the G30 codes may be appropriate.

§Providers should contact their local commercial payers and Medicaid plans for specific information or additional coding requirements for Alzheimer's disease under ICD-10 codes.

||Information sourced from CMS Memo August 17, 2023.

CPT=Current Procedural Technology; FDA= US Food and Drug Administration; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; IV=Intravenous; NDC=National Drug Code; NPI=National Provider Identifier.