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

Coding for LEQEMBI®

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.

INDICATION

LEQEMBI is indicated for the treatment of Alzheimer's disease. Treatment with LEQEMBI should be initiated in patients with mild cognitive impairment 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 amyloid beta, including LEQEMBI, can cause amyloid related imaging abnormalities (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 rarely can occur. Serious intracerebral hemorrhages >1 cm, some of which have been fatal, have been observed in patients treated with this class of medications.**
  - **Apolipoprotein E ε4 (ApoE ε4) Homozygotes: Patients who are ApoE ε4 homozygotes (approximately 15% of Alzheimer's disease patients) treated with this class of medications, including LEQEMBI, 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 Alzheimer's disease and potential risk of serious adverse events associated with ARIA when deciding to initiate treatment with LEQEMBI.**

CONTRAINDICATION

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

RECOMMENDED DOSAGE

The recommended dosage of LEQEMBI is 10 mg/kg that must be diluted then administered as an intravenous infusion over approximately one hour, once every two weeks.

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

HCPCS code 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. Some payers may not have updated their HCPCS code files as of yet and until doing so may require the unclassified J code as listed below. Providers should contact their local commercial payers and Medicaid plans for specific information on reporting drugs using unclassified HCPCS codes.

Code*	Description
J0174	Injection, lecanemab-irmb, 1 mg
J3590	Unclassified biologics
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 modifier. Effective July 1, 2023, Medicare requires the JZ modifier on all claims for single-dose containers where there are no discarded amounts. Check with other payers to determine if they have similar requirements.

Hospital outpatient revenue codes

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

CPT code for drug administration service

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, eg, 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, so stated

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

Billing Medicare for LEQEMBI®

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. Claims can be submitted on or after July 25, 2023. 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 require additional registry coding information on claims. Please confirm with the plan sponsor[§]
- Use HCPCS code J0174 (Injection, lecanemab-irmb, 1 mg)
- 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
- 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 above
- Institutional claims:
  - 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, 7/6/2023 and CMS Memo, 8/17/2023.

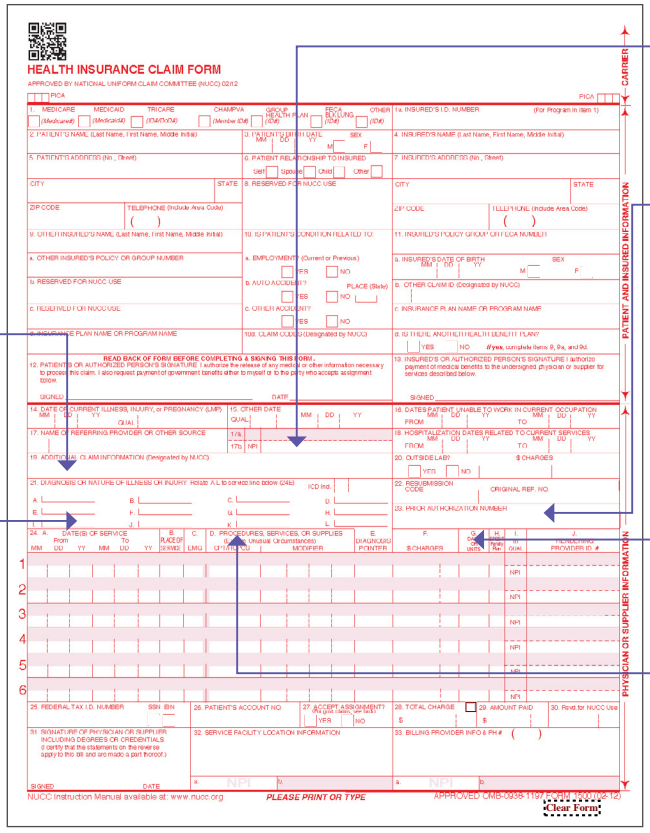
Please visit **https://qualitynet.cms.gov/alzheimers-ced-registry** for additional information and updates.

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.

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. For a product with an unclassified J Code, provide in this box the commentary for the drug name, route of administration, amount administered, and amount discarded

FIELD 21 (Loop 2300):
Provide the most appropriate diagnosis code(s). For Medicare registry enrollees, report ICD-10 diagnosis code Z00.6 in the primary or secondary position



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 Important 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.

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

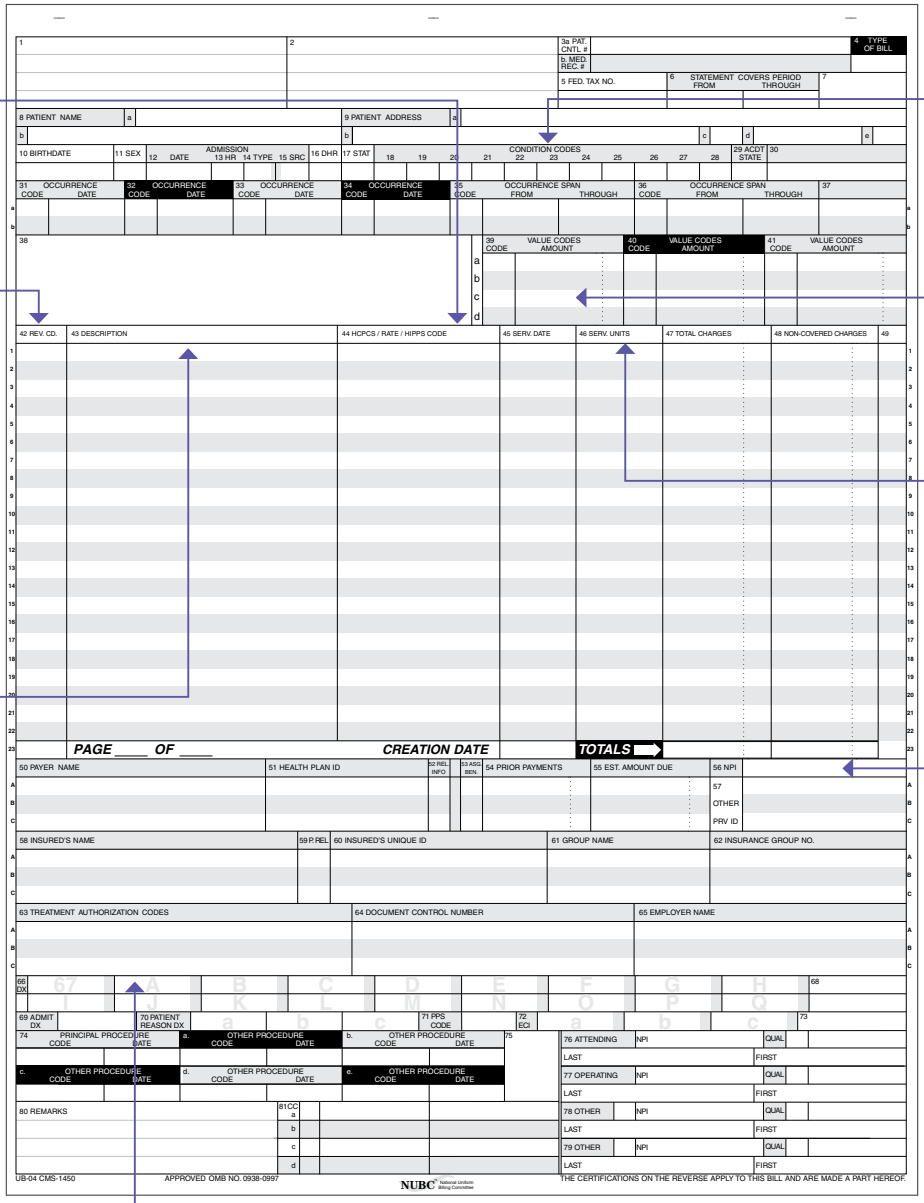
FIELD 42 (Loop 2400):

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



FIELD 67 (Loop 2300):

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

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

Please see Important 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

- LEQEMBI can cause ARIA-E and ARIA-H. ARIA-E can be observed on MRI as brain edema or sulcal effusions, and ARIA-H as microhemorrhage and superficial siderosis. ARIA can occur spontaneously in patients with Alzheimer's disease. ARIA-H associated with monoclonal antibodies directed against aggregated forms of beta amyloid generally occurs in association with an occurrence of ARIA-E. ARIA-H and ARIA-E can occur together.
- ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events, including seizure and status epilepticus, rarely can occur. Reported symptoms associated with ARIA may include headache, confusion, visual changes, dizziness, nausea, and gait difficulty. Focal neurologic deficits may also occur. Symptoms associated with ARIA usually resolve over time.

ARIA Monitoring and Dose Management Guidelines

- Obtain recent baseline brain magnetic resonance imaging (MRI) prior to initiating treatment with LEQEMBI. Obtain an MRI prior to the 5th, 7th and 14th infusions.
- Recommendations for dosing in patients with ARIA-E and ARIA-H depend on clinical symptoms and radiographic severity. Depending on ARIA severity, use clinical judgment in considering whether to continue dosing, temporarily discontinue treatment, or permanently discontinue LEQEMBI.
- Enhanced clinical vigilance for ARIA is recommended during the first 14 weeks of treatment with LEQEMBI. If a patient experiences symptoms suggestive of ARIA, 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.
- There is no experience in patients who continued dosing through symptomatic ARIA-E or through asymptomatic, but radiographically severe, ARIA-E. There is limited experience in patients who continued dosing through asymptomatic but radiographically mild to moderate ARIA-E. There are limited data in dosing patients who experienced recurrent ARIA-E.

Incidence of ARIA

- In Study 2, symptomatic ARIA occurred in 3% (29/898) of LEQEMBI-treated patients. Serious symptoms associated with ARIA were reported in 0.7% (6/898) of patients treated with LEQEMBI. Clinical symptoms associated with ARIA resolved in 79% (23/29) of patients during the period of observation.
- Including asymptomatic radiographic events, ARIA was observed in LEQEMBI: 21% (191/898); placebo: 9% (84/897). ARIA-E was observed in LEQEMBI: 13% (113/898); placebo: 2% (15/897). ARIA-H was observed in LEQEMBI: 17% (152/898); placebo: 9% (80/897). There was no increase in isolated ARIA-H for LEQEMBI vs placebo.

ApoE ε4 Carrier Status and Risk of ARIA

- In Study 2, 16% (141/898) of patients in the LEQEMBI arm were ApoE ε4 homozygotes, 53% (479/898) were heterozygotes, and 31% (278/898) were noncarriers.
- The incidence of ARIA was higher in ApoE ε4 homozygotes (LEQEMBI: 45%; placebo: 22%) than in heterozygotes (LEQEMBI: 19%; placebo: 9%) and noncarriers (LEQEMBI: 13%; placebo: 4%). Among patients treated with LEQEMBI, symptomatic ARIA-E occurred in 9% of ApoE ε4 homozygotes compared with 2% of heterozygotes and 1% of noncarriers. Serious events of ARIA occurred in 3% of ApoE ε4 homozygotes, and approximately 1% of heterozygotes and noncarriers.
- The recommendations on management of ARIA do not differ between ApoE ε4 carriers and noncarriers.

Radiographic Findings

- The majority of ARIA-E radiographic events occurred early in treatment (within the first 7 doses), although ARIA can occur at any time and patients can have more than 1 episode. The maximum radiographic severity of ARIA-E in patients treated with LEQEMBI was mild in 4% (37/898), moderate in 7% (66/898), and severe in 1% (9/898). Resolution on MRI occurred in 52% of ARIA-E patients by 12 weeks, 81% by 17 weeks, and 100% overall after detection. The maximum radiographic severity of ARIA-H microhemorrhage in LEQEMBI-treated patients was mild in 9% (79/898), moderate in 2% (19/898), and severe in 3% (28/898) of patients; superficial siderosis was mild in 4% (38/898), moderate in 1% (8/898), and severe in 0.4% (4/898). Among LEQEMBI-treated patients, the rate of severe radiographic ARIA-E was highest in ApoE ε4 homozygotes 5% (7/141), compared to heterozygotes 0.4% (2/479) or noncarriers 0% (0/278). Among LEQEMBI-treated patients, the rate of severe radiographic ARIA-H was highest in ApoE ε4 homozygotes 13.5% (19/141), compared to heterozygotes 2.1% (10/479) or noncarriers 1.1% (3/278).

Intracerebral Hemorrhage

- Intracerebral hemorrhage >1 cm in diameter was reported in 0.7% (6/898) of patients in Study 2 after treatment with LEQEMBI compared to 0.1% (1/897) on placebo. Fatal events of intracerebral hemorrhage in patients taking LEQEMBI have been reported.

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

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Concomitant Antithrombotic Medication:

- In Study 2, baseline use of antithrombotic medication (aspirin, other antiplatelets, or anticoagulants) was allowed if the patient was on a stable dose. The majority of exposures to antithrombotic medications were to aspirin. Antithrombotic medications did not increase the risk of ARIA with LEQEMBI. The incidence of intracerebral hemorrhage was 0.9% (3/328 patients) in patients taking LEQEMBI with a concomitant antithrombotic medication at the time of the event compared to 0.6% (3/545 patients) in those who did not receive an antithrombotic. Patients taking LEQEMBI with an anticoagulant alone or combined with an antiplatelet medication or aspirin had an incidence of intracerebral hemorrhage of 2.5% (2/79 patients) compared to none in patients who received placebo.
- Because intracerebral hemorrhages >1 cm in diameter have been observed in patients taking LEQEMBI, additional caution should be exercised when considering the administration of anticoagulants or a thrombolytic agent (e.g., tissue plasminogen activator) to a patient already being treated with LEQEMBI.

Other Risk Factors for Intracerebral Hemorrhage:

- Patients were excluded from enrollment in Study 2 for findings on neuroimaging that indicated an increased risk for intracerebral hemorrhage. These included findings suggestive of cerebral amyloid angiopathy (prior cerebral hemorrhage >1 cm in greatest diameter, >4 microhemorrhages, superficial siderosis, vasogenic edema) or other lesions (aneurysm, vascular malformation) that could potentially increase the risk of intracerebral hemorrhage. The presence of an ApoE ε4 allele is also associated with cerebral amyloid angiopathy, which has an increased risk for intracerebral hemorrhage. Caution should be exercised when considering the use of LEQEMBI in patients with factors that indicate an increased risk for intracerebral hemorrhage and in particular for patients who need to be on anticoagulant therapy.

HYPERSENSITIVITY REACTIONS

Hypersensitivity reactions, including angioedema, bronchospasm, and anaphylaxis, have occurred in LEQEMBI-treated patients. 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

- In Study 2, infusion-related reactions were observed in LEQEMBI: 26% (237/898); placebo: 7% (66/897), and the majority of cases in LEQEMBI-treated patients (75%, 178/237) occurred with the first infusion. Infusion-related reactions were mostly mild (69%) or moderate (28%) in severity. Infusion-related reactions resulted in discontinuations in 1% (12/898) of LEQEMBI-treated patients. Symptoms of infusion-related reactions included fever and flu-like symptoms (chills, generalized aches, feeling shaky, and joint pain), nausea, vomiting, hypotension, hypertension, and oxygen desaturation.
- In the event of an infusion-related reaction, the infusion rate may be reduced, or the infusion may be discontinued, and appropriate therapy initiated as clinically indicated. Prophylactic treatment with antihistamines, acetaminophen, nonsteroidal anti-inflammatory drugs, or corticosteroids prior to future infusions may be considered.

ADVERSE REACTIONS

- In Study 2, the most common adverse reaction leading to discontinuation of LEQEMBI was ARIA-H microhemorrhages that led to discontinuation in 2% (15/898) of patients treated with LEQEMBI compared to <1% (1/897) of patients on placebo.
- In Study 2, the most common adverse reactions reported in ≥5% of patients treated with LEQEMBI (N=898) and ≥2% higher than placebo (N=897) were infusion-related reactions (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.

‡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 8/17/2023.

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