

BILLING AND CODING GUIDE

INDICATION

Kisunla is indicated for the treatment of Alzheimer's disease (AD). Treatment with Kisunla should be initiated in patients with mild cognitive impairment (MCI) or mild dementia stage of disease, the population in which treatment was initiated in the clinical trials.

SELECT IMPORTANT SAFETY INFORMATION

WARNING: AMYLOID-RELATED IMAGING ABNORMALITIES

Monoclonal antibodies directed against aggregated forms of beta amyloid, including Kisunla, can cause amyloid-related imaging abnormalities (ARIA), characterized as ARIA with edema (ARIA-E) and ARIA with hemosiderin deposition (ARIA-H). ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events can occur. ARIA can be fatal. Serious intracerebral hemorrhages >1 cm, some of which have been fatal, have been observed in patients treated with this class of medications. 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 Kisunla.

ApoE ϵ 4 Homozygotes: Patients who are apolipoprotein E ϵ 4 (ApoE ϵ 4) homozygotes treated with this class of medications, including Kisunla, have a higher incidence of ARIA, including symptomatic, serious, and severe radiographic ARIA, compared to heterozygotes and noncarriers. Testing for ApoE ϵ 4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA. Prior to testing, the risk of ARIA across genotypes and implications of genetic testing results should be discussed with patients.

Consider the benefit for the treatment of Alzheimer's disease and risk of ARIA when deciding to treat with Kisunla.

Please see additional [Important Safety Information](#) and full [Prescribing Information](#), including Boxed Warning for ARIA, and [Medication Guide](#) for Kisunla.

INTRODUCTION

Lilly is committed to providing you with reimbursement information for Kisunla. This Billing and Coding Guide has been developed to provide information regarding:

- Essential Coding Considerations
- Important Product Information
- Sample Claims Forms
- Reimbursement Support Resources

This guide is intended to be an educational reference, providing general information regarding coding and billing of Kisunla. This guide is offered for informational purposes only and is not intended to provide reimbursement or legal advice. Each healthcare provider or healthcare entity is responsible for determining the appropriate codes, coverage, and payment for individual patients. Lilly does not guarantee third-party coverage or payment for denied claims.

Providers should always verify coverage prior to initiating therapy and determine the appropriate codes on a case-by-case basis. Insurance coverage, coding, claims filing, and reimbursement vary by setting of care as well as payer type.

Although Lilly has made every effort to be current as of the publication of this guide, the information is subject to change. Similarly, all CPT® and HCPCS codes are supplied for informational purposes only. This information does not represent any statement, promise, or guarantee by Lilly about coverage, levels of reimbursement, payment, availability, or charge. Additional information may exist, and actual coverage and reimbursement decisions are made by individual payers. Providers should contact the applicable third-party payers for specific information on coding and billing requirements.

Your Field Reimbursement Manager is an experienced access professional who is committed to helping navigate the complex access and reimbursement environment to help patients get access to Kisunla. For more information, including information about Kisunla access and reimbursement, visit <https://kisunla.lilly.com/hcp/support-resources> or call Lilly Support Services at 1-800-LillyRx (1-800-545-5979).

CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System.
CPT® is a registered trademark of the American Medical Association.

SELECT IMPORTANT SAFETY INFORMATION

- **Hypersensitivity: Kisunla is contraindicated** in patients with known serious hypersensitivity to donanemab-azbt or to any of the excipients. Reactions have included anaphylaxis.

Amyloid-Related Imaging Abnormalities (ARIA)

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. When present, reported symptoms associated with ARIA may include, but are not limited to, headache, confusion, visual changes, dizziness, nausea, and gait difficulty. Focal neurologic deficits may also occur. Symptoms associated with ARIA usually resolve over time.

Please see additional [Important Safety Information](#) and full [Prescribing Information](#), including Boxed Warning for ARIA, and [Medication Guide](#) for Kisunla.

TABLE OF CONTENTS

04 [CENTERS FOR MEDICARE & MEDICAID SERVICES \(CMS\) COVERS KISUNLA UNDER COVERAGE WITH EVIDENCE DEVELOPMENT \(CED\)](#)

[04 National Coverage Determination \(NCD\) on Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer’s Disease \(AD\) \(200.3\)](#)

[04 CMS Registry Coding Requirements](#)

05 [HOW KISUNLA IS SUPPLIED](#)

05 [CODING FOR KISUNLA](#)

[05 ICD-10-CM Diagnosis Codes](#)

[06 Healthcare Common Procedure Coding System \(HCPCS\) Level II Codes \(eg, J-codes\)](#)

[07 National Drug Code \(NDC\)](#)

[08 Intravenous \(IV\) Infusion Administration Codes](#)

09 [OTHER CODING CONSIDERATIONS](#)

[09 Registry Modifiers](#)

[09 Registry Number](#)

[10 Wastage Modifiers](#)

[11 Place of Service \(POS\) Codes](#)

[12 Revenue Codes](#)

[13 Same-Day Evaluation and Management Services](#)

[13 Magnetic Resonance Imaging \(MRI\) Codes](#)

14 [SAMPLE CLAIMS FORMS](#)

[14–15 Physician Office and Freestanding Infusion Center Sample Claim Form \(CMS-1500\)](#)

[16–17 Hospital Outpatient Sample Claim Form \(CMS-1450\)](#)

18 [IMPORTANT SAFETY INFORMATION WITH WARNINGS](#)

ALL MEDICARE PLANS AND CONTRACTORS COVER AMYLOID-TARGETING THERAPIES (ATTS), INCLUDING KISUNLA, UNDER COVERAGE WITH EVIDENCE DEVELOPMENT (CED)^{1,2,8}

NATIONAL COVERAGE DETERMINATION (NCD) ON MONOCLONAL ANTIBODIES DIRECTED AGAINST AMYLOID FOR THE TREATMENT OF ALZHEIMER’S DISEASE (AD) (200.3)^{1,2}

Covered population¹:

- Patients who have a clinical diagnosis of MCI due to AD or mild AD dementia, both with confirmed presence of amyloid beta pathology consistent with AD

Coverage criteria—drugs in class that receive traditional FDA approval¹:

- Patient must be enrolled in Medicare
- Patients must have a diagnosis of MCI due to AD or mild AD dementia, with documented evidence of beta-amyloid plaques in the brain
- Physician must participate in a qualifying registry* with an appropriate clinical team and follow-up care[†]

For more information on the CMS National Patient Registry for monoclonal antibodies directed against amyloid for the treatment of AD, visit <https://qualitynet.cms.gov/alzheimers-ced-registry>

*For more information on qualifying registries, visit <https://www.cms.gov/medicare/coverage/coverage-evidence-development/monoclonal-antibodies-directed-against-amyloid-treatment-alzheimers-disease-ad>

CMS REGISTRY CODING REQUIREMENTS

Based on the CED requirements, CMS requires additional codes and modifiers as part of a claim for treatment with Kisunla.³ These may include:

- **Diagnosis codes:** Must include both Z00.6 (to denote clinical research participation) AND an appropriate AD diagnosis code ([see page 5](#) for more information)^{3,4}
- **Registry modifiers:** Must include either Q0 or Q1 to note participation in a registry ([see page 9](#) for more information)^{3,5}
- **Registry number:** If the patient is enrolled in the CMS National Patient Registry, please use NCT 06058234. If the patient is enrolled in a different CMS-approved CED registry, please use the assigned Clinicaltrials.gov number as appropriate ([see page 9](#) for more information)^{3,6,7}

In addition, institutional claims using the UB-04/CMS-1450 form require the following information³:

- **Type of bill:** 12X, 13X, or 85X
- **Revenue code:** 0636
- **Condition code:** 30

[†]Prescribing clinicians or their staff shall submit at first baseline treatment via the dedicated CMS CED data submission portal and every 6 months for up to 24 months (5 total assessments).⁷
MCI=mild cognitive impairment.

SELECT IMPORTANT SAFETY INFORMATION

Risk Factors for ARIA and Intracerebral Hemorrhages (ICH)

- **ApoE ε4 Carrier Status:** The risk of ARIA, including symptomatic and serious ARIA, is increased in apolipoprotein E ε4 (ApoE ε4) homozygotes.
- Recommendations for management of ARIA do not differ based on ApoE ε4 carrier status. Testing for ApoE ε4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA.

Please see additional [Important Safety Information](#) and full [Prescribing Information](#), including Boxed Warning for ARIA, and [Medication Guide](#) for Kisunla.

HOW KISUNLA IS SUPPLIED

Kisunla is supplied in single-dose vials (350 mg/20 mL [17.5 mg/mL]) as a sterile, preservative-free, clear to opalescent, colorless to slightly yellow to slightly brown solution.⁸

ICD-10-CM DIAGNOSIS CODES*

Coding System	Code Numbers	Description of Diagnosis Code	Location on CMS-1500 Payer Form (Electronic Equivalent)	Location on CMS-1450/UB-04 Form (Electronic Equivalent)	Comments
ICD-10 diagnosis code ⁴	CMS Registry Modifier		Field 21	Field 67	For CMS billing, providers must include Z00.6 in addition to one of the AD diagnosis codes listed in the chart. Providers should use current ICD-10 codes to report a patient’s diagnosis on claim submissions. The list of ICD-10 diagnosis codes provided on the left may be reasonably related to a diagnosis within the product’s approved label. Other codes may be appropriate. Correct coding is the responsibility of the provider submitting a claim for the item or service. Please see FDA-approved indication for Kisunla and check with the payer to verify coding or special billing requirements. There are no specific codes currently available for a diagnosis of MCI due to Alzheimer’s disease. G31.84 should be used in addition to a G30-code to indicate a diagnosis of AD with MCI.
	Z00.6	Encounter for examination for normal comparison and control in clinical research program	Enter in the appropriate diagnosis code in lines A-L to identify the patient’s diagnosis or condition and the applicable ICD indicator to identify which ICD code version is being reported. Use the highest level of specificity.		
	Alzheimer’s Disease				
	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				
	G31.84	MCI of uncertain or unknown etiology			

*These codes are not intended to be promotional or to encourage or suggest a use of drug that is inconsistent with US FDA-approved use. The codes provided are not exhaustive and additional codes may apply. Listed codes may require a higher level of specificity when reporting for individual patients. Please note that providers are responsible for selecting appropriate codes for any particular claim based on the patient’s diagnosis, the items and services that are furnished, and any specific payer requirements. It is advisable to contact your local payer with regard to local payment policies.



HCPCS LEVEL II CODES (eg, J-CODES)

Provider-administered drugs are typically reported using product-specific HCPCS codes (eg, J-codes) assigned by CMS. Kisunla was issued the permanent J-code listed below, effective July 2, 2024. All claims for dates of service on or after July 2, 2024, should use this permanent J-code to facilitate reimbursement.³

Coding System	Code (Description)	Location on CMS-1500 Payer Form (Electronic Equivalent)	Location on CMS-1450/ UB-04 Form (Electronic Equivalent)	Comments
HCPCS ³	J0175: Injection, donanemab-azbt, 2mg	Field 24D	Field 44	When billing for Kisunla using J0175 1 unit=2 mg. Report 175 units (350 mg) for infusion one, 350 units (700 mg) for infusion two, 525 units (1050 mg) for infusion three, and 700 units (1400 mg) for infusion four and beyond. ^{3,8}
	Enter the number of units	Field 24G	Field 46	

SELECT IMPORTANT SAFETY INFORMATION

Risk Factors for ARIA and Intracerebral Hemorrhages (ICH) (continued)

- **Radiographic Findings of Cerebral Amyloid Angiopathy (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, were identified as risk factors for ARIA. Patients were excluded from enrollment for findings on neuroimaging of prior ICH >1 cm in diameter, >4 microhemorrhages, >1 area of superficial siderosis, severe white matter disease, and vasogenic edema.

Please see additional [Important Safety Information](#) and full [Prescribing Information](#), including Boxed Warning for ARIA, and [Medication Guide](#) for Kisunla.

NATIONAL DRUG CODE (NDC)

The NDC is a unique number that identifies a drug’s labeler, product, and trade package size.⁹ The NDC has historically been primarily used for pharmacy billing. However, certain insurance companies have set requirements that all medications be billed with the NDC method, while others may or may not optionally accept NDC billing for claims. For example, Medicaid fee-for-service programs, Medicare crossover claims for dual-eligible beneficiaries, and some commercial payers now also require the NDC for billing instead of, or in addition to, the HCPCS code, for physician claims and those of other service providers.¹⁰

Although the FDA uses a 10-digit format when registering NDCs, payer requirements regarding the use of the 10- or 11-digit NDC may vary. Electronic data exchange generally requires use of the 11-digit NDC in a 5-4-2 format. To convert the 10-digit format to the 11-digit format, insert a leading zero into the appropriate sequence position, as illustrated below.⁹

NDC Format	NDC	Location on CMS-1500 Payer Form (Electronic Equivalent)	Location on CMS-1450/ UB-04 Form (Electronic Equivalent)	Comments
10-digit NDC ⁹	0002-9401-01	Field 19	Field 80	To convert the 10-digit format to the 11-digit 5-4-2 format, insert a leading zero into the appropriate sequence position, as illustrated. ⁹
11-digit NDC ⁹	00002-9401-01			

IV INFUSION ADMINISTRATION CODES

This section reviews general coding guidelines for drug administration services coded by physician offices and noninstitutional providers using the CMS-1500 claim form and by institutional providers, including hospital outpatient departments using the CMS-1450 (UB-04) claim form. Drug administration services are reported using the CPT® coding system.^{11,12}

Coding System	Code (Description)	Location on CMS-1500 Payer Form (Electronic Equivalent)	Location on CMS-1450/ UB-04 Form (Electronic Equivalent)	Comments
CPT ¹³	96413: Chemotherapy administration, IV infusion technique; up to 1 hour, single or initial substance/drug	Field 24D	Field 44	Payer requirements regarding the use of 96413 or 96365 may vary. Consult payer policies for specific requirements. When billing 96413 or 96365 for Kisunla, 1 unit = 1 infusion.
	96365: IV infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour			
	Enter the number of units	Field 24G	Field 46	

Kisunla is administered via IV infusion over approximately 30 minutes. Patients should be monitored post-infusion for a minimum of 30 minutes to evaluate for infusion and hypersensitivity reactions.⁸
IV=intravenous.

SELECT IMPORTANT SAFETY INFORMATION

Risk Factors for ARIA and Intracerebral Hemorrhages (ICH) (continued)

- **Concomitant Antithrombotic or Thrombolytic Medication:** In Study 1, the majority of exposures to antithrombotic medications were to aspirin. The number of events and the limited exposure to non-aspirin antithrombotic medications limit definitive conclusions about the risk of ARIA or ICH in patients taking antithrombotic medications. Additional caution should be exercised when considering the administration of antithrombotics or a thrombolytic agent (eg, tissue plasminogen activator) to a patient already being treated with Kisunla. One fatal ICH occurred in a patient taking Kisunla in the setting of focal neurologic symptoms of ARIA and the use of a thrombolytic agent in Study 1, and one fatal intracerebral hemorrhage occurred in the setting of ARIA and the use of a thrombolytic agent in Study 2.
- Consider whether ischemic stroke symptoms could be due to ARIA-E before giving thrombolytic therapy in a patient being treated with Kisunla, because ARIA-E can cause focal neurologic deficits that can mimic an ischemic stroke.
- Caution should be exercised when considering the use of Kisunla in patients with factors that indicate an increased risk for ICH and in particular for patients who need to be on anticoagulant therapy or patients with findings on MRI that are suggestive of CAA.

Please see additional [Important Safety Information](#) and full [Prescribing Information](#), including Boxed Warning for ARIA, and [Medication Guide](#) for Kisunla.

REGISTRY MODIFIERS

Based on CMS policy, additional modifiers may be required if the provider is submitting claims for Kisunla to note a patient’s participation in a CMS National Patient Registry or any other CMS-approved study (per the NCD requirements).

Modifier ⁵	Location on CMS-1500 Payer Form (Electronic Equivalent)	Location on CMS-1450/ UB-04 Form (Electronic Equivalent)	Comments ⁵
Q0	Field 24D	Field 44	Used to note investigational clinical service provided in a clinical research study that is in an approved clinical research study.
Q1			Used to note routine clinical service provided in a clinical research study that is in an approved clinical research study.

REGISTRY NUMBER

Coding System	Code (Description)	Location on CMS-1500 Payer Form (Electronic Equivalent)	Location on CMS-1450/ UB-04 Form (Electronic Equivalent)	Comments
Registry trial number (8 digits)	NCT 06058234 for the CMS Medicare Anti-Aβ mAb CED Study ⁷	Box 19	Field 39 Enter value code D4 and the 8-digit clinical trial number ¹⁴	Each CMS-approved CED registry will have a unique Clinicaltrials.gov identifier number to be included on the claim. Please verify the appropriate clinical trial number based on the CED registry in which the patient is enrolled. For example, enter Clinicaltrials.gov number NCT 06058234 for Medicare patients participating in the CMS Medicare Anti-Aβ mAb CED study. ⁷
	Registry-specific code (Each CMS-approved CED registry will have a unique Clinicaltrials.gov identifier number to be included on the claim. Please verify the appropriate clinical trial number based on the CED registry in which the patient is enrolled.)			

Aβ=amyloid beta; mAb=monoclonal antibody.

For more information about available registries, visit <https://www.cms.gov/medicare/coverage/coverage-evidence-development/monoclonal-antibodies-directed-against-amyloid-treatment-alzheimers-disease-ad>



WASTAGE MODIFIERS

- In addition, CMS requires additional modifiers to document any drug wastage, or to note that there was no wastage.¹⁵
- The modifier JZ is a HCPCS Level II Claim modifier effective July 1, 2023, with providers and suppliers required to report the JZ modifier on all claims for drugs from single-dose containers when there are no discarded amounts. The new modifier policy for both JW and JZ applies to all drugs separately payable under Medicare Part B that are described as being supplied in a “single-dose” container or “single-use” package based on FDA-approved labeling, and will apply to claims from physician’s office, HOPD, and CAH
 - Providers and suppliers are required to report the JW modifier on all claims that bill for drugs and biologicals separately payable under Medicare Part B with unused and discarded amounts from single-dose containers or single-use packages (hereafter, single-dose containers)

Modifier ¹⁶	Location on CMS-1500 Payer Form (Electronic Equivalent)	Location on CMS-1450/ UB-04 Form (Electronic Equivalent)	Comments ¹⁶
JZ	Field 24D	Field 44	Used if there is zero drug amount discarded/not administered to any patient. JZ modifier should be billed on the same line as the product administered.
JW			Used if there is any drug amount discarded/not administered to the patient. JW modifier should be used on a separate line noting the amount of product discarded.

CAH=critical access hospital; HOPD=hospital outpatient department.

SELECT IMPORTANT SAFETY INFORMATION

ARIA Monitoring and Dose Management Guidelines

- Baseline brain MRI and periodic monitoring with MRI are recommended prior to the 2nd, 3rd, 4th, and 7th infusions. Enhanced clinical vigilance for ARIA is recommended during the first 24 weeks of treatment with Kisunla. 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.
- 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, interrupt treatment, or permanently discontinue Kisunla. See Prescribing Information for additional dosing considerations.

Please see additional [Important Safety Information](#) and full [Prescribing Information](#), including Boxed Warning for ARIA, and [Medication Guide](#) for Kisunla.

PLACE OF SERVICE (POS) CODES

POS codes are included to indicate where the infusion was administered.

POS Code ¹⁷	POS Name ¹⁷	Location on CMS-1500 Payer Form (Electronic Equivalent)	POS Description ¹⁷
11	Office	Field 24B	Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, state or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.
19	Off Campus-Outpatient Hospital		A portion of an off-campus hospital provider-based department which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.
21	Inpatient Hospital		A facility, other than psychiatric, which primarily provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services by, or under, the supervision of physicians to patients admitted for a variety of medical conditions.
22	On Campus-Outpatient Hospital		A portion of a hospital’s main campus which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.
49	Independent Clinic		A location, not part of a hospital and not described by any other POS code, that is organized and operated to provide preventive, diagnostic, therapeutic, rehabilitative, or palliative services to outpatients only.

REVENUE CODES

Revenue codes are required for hospital outpatient billing and will vary depending on the revenue center to which the hospital maps Kisunla. Typically, Kisunla will be reported using the revenue codes listed below.

Coding System	Code and Description ¹⁸	Location on CMS-1450/UB-04 Form	Comments
AHA Revenue System ¹⁸	0250 (Pharmacy—general classification)	Field 42 (code)	Revenue code requirements for claims with a CPT® code for IV infusion may vary.
	0636 (Drug requiring detailed coding)	Field 43 (description of service)	
	0260 (IV therapy—general classification)		
	0262 (IV therapy—IV therapy/pharmacy services)		
	0510 (Clinic—general classification)		

SAME-DAY EVALUATION AND MANAGEMENT SERVICES

It may be necessary to provide evaluation and management services on the same day as a drug administration procedure. Depending on the payer, evaluation and management services that are medically necessary, separate, distinct from the drug administration procedure, and documented appropriately are generally covered.

Please note that CMS has a specific policy regarding use of CPT code 99211 (level 1 medical visit for an established patient) in the physician office. The policy states: CPT code 99211 cannot be paid if it is billed, with or without modifier -25, with a chemotherapy or nonchemotherapy drug administration code 12. Thus, CPT code 99211 cannot be paid on the same day as an office-based infusion of Kisunla.

However, when a medically necessary, significant and separately identifiable E/M service (which meets a higher complexity level than CPT code 99211) is performed, in addition to the drug administration service(s), the appropriate E/M CPT code should be reported with modifier -25. If a therapeutic or complex drug administration service and a significantly identifiable, distinct evaluation and management service are provided on the same day, a different diagnosis is not required.^{19, 20}

SELECT IMPORTANT SAFETY INFORMATION

Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis and angioedema, have occurred in patients who were treated with Kisunla. 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 (IRR)

IRRs were observed with Kisunla with the majority occurring within the first 4 infusions. Most IRRs occurred during the infusion or within 30 minutes after completion of the infusion, however some have occurred hours after an infusion. Signs and symptoms of IRRs include chills, erythema, nausea/vomiting, flushing, difficulty breathing/dyspnea, sweating, elevated blood pressure, headache, chest pain, and low blood pressure. In the event of an IRR, the infusion rate may be reduced, or the infusion may be discontinued, and appropriate therapy initiated as clinically indicated. Consider pre-treatment with antihistamines, acetaminophen, or corticosteroids prior to subsequent dosing.

MRI CODES

MRIs are required throughout the course of treatment with Kisunla for detection and monitoring of ARIA.⁸ The following CPT code may be used to document MRI use¹³:

- 70551: Magnetic resonance (eg, proton) imaging, brain (including brain stem); without contrast material.

ARIA=amyloid-related imaging abnormalities; E/M=evaluation and management; MRI=magnetic resonance imaging.

Please see additional [Important Safety Information](#) and full [Prescribing Information](#), including Boxed Warning for ARIA, and [Medication Guide](#) for Kisunla.



SAMPLE CLAIM FORM (CMS-1500)

The Form CMS-1500 is the basic form prescribed by CMS for the Medicare and Medicaid programs for claims from suppliers and noninstitutional providers who qualify for a waiver from the Administrative Simplification Compliance Act (ASCA) requirement for electronic submission of claims. It has also been adopted by the TRICARE® Program.^{11,21} For detailed guidance on completing the CMS-1500 items, please see the Medicare Claims Processing Manual, Pub. 100-04, Chapter 26, available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26.pdf>

FIELD 19: ADDITIONAL CLAIM INFORMATION

For patients with Medicare participating in the CMS National Patient Registry for monoclonal antibodies directed against amyloid for the treatment of AD, use NCT number 06058234.⁷ If the patient is enrolled in a different CMS-approved CED registry, please use the assigned Clinicaltrials.gov number as appropriate. Please see page 7 for NDC number and page 9 for registry numbers.

FIELD 21: DIAGNOSIS OR NATURE OF ILLNESS OR INJURY

Enter the appropriate diagnosis code in lines A-L to identify the patient's diagnosis/condition and the applicable ICD indicator to identify which ICD code version is being reported. Use the highest level of specificity. Be sure to also include Z00.6 to denote participation in a clinical research program, as appropriate.⁴ Please see page 5 for ICD-10-CM codes.

FIELD 24B: PLACE OF SERVICE NUMBER

Enter the appropriate place of service number. Please see page 11 for place of service codes.

FIELD 24D: PROCEDURES, SERVICES, OR SUPPLIES

Enter the HCPCS and CPT® code for the administration of Kisunla. Be sure to also enter the appropriate HCPCS modifiers on the same line, including either Q0 or Q1 if the patient is enrolled in a CMS registry.⁵ Note if the full single dose was administered or if any portion was discarded; append the appropriate modifier JW, JZ. Please see page 6 for HCPCS codes, page 8 for CPT codes, and pages 9 and 10 for HCPCS modifiers.

FIELD 24E: DIAGNOSIS POINTER

Enter the diagnosis code reference letter (A-L) as shown in Field 21 to relate the date of service and the procedures performed to the primary diagnosis. The first pointer designates the primary diagnosis for the procedures and any remaining diagnosis pointers indicate declining level of importance to procedures.

FIELD 24G: DAYS OR UNITS

Enter the appropriate units for the HCPCS and CPT code. When billing for Kisunla using J0175, 1 unit = 2 mg. Report 175 units (350 mg) for infusion one, 350 units (700 mg) for infusion two, 525 units (1050 mg) for infusion three, and 700 units (1400 mg) for infusion four and beyond.^{3,8} When billing 96413 or 96365 for Kisunla, 1 unit = 1 infusion.

SELECT IMPORTANT SAFETY INFORMATION

Adverse Reactions

The most common adverse reactions reported in ≥5% of patients treated with Kisunla and ≥2% higher than placebo: ARIA-H microhemorrhage, ARIA-E, ARIA-H superficial siderosis, headache, and IRRs.

Please see additional Important Safety Information and full Prescribing Information, including Boxed Warning for ARIA, and Medication Guide for Kisunla.

All coding and documentation requirements for drugs should be confirmed with each payer.

HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

1. MEDICARE MEDICAID TRICARE CHAMPVA GROUP HEALTH PLAN FECA BULK LUNG OTHER

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE SEX

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED

7. INSURED'S ADDRESS (No., Street)

8. RESERVED FOR NUCC USE

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP)

15. OTHER DATE

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a. NPI

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB?

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E)

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE B. PLACE OF SERVICE C. EMG D. PROCEDURES, SERVICES, OR SUPPLIES E. DIAGNOSIS POINTER

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back)

28. TOTAL CHARGE

29. AMOUNT PAID

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

32. SERVICE FACILITY LOCATION INFORMATION

33. BILLING PROVIDER INFO & PH #

SIGNED DATE

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)

For more information, please visit www.nucc.org and www.cms.gov.

HOSPITAL OUTPATIENT

SAMPLE CLAIM FORM (CMS-1450)

The Form CMS-1450, also known as the UB-04, is a uniform institutional provider bill suitable for use in billing multiple third-party payers. It is the basic form prescribed by CMS for the Medicare and Medicaid programs for claims from hospitals, including HOPDs. Because it serves many payers, a particular payer may not need some data elements.¹² For detailed guidance on completing the CMS-1450 items, please see the Medicare Claims Processing Manual, Pub. 100-04, Chapter 25, available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf>

FIELD 04: TYPE OF BILL

Enter the appropriate type of bill based on the facility type.²²
012X: Hospital Inpatient (Part B)
013X: Hospital Outpatient
085X: CAH

FIELD 18: CONDITION CODE

For patients enrolled in a CMS-approved CED registry, enter condition code 30.^{3,5}

FIELD 39: VALUE CODE

Enter value code D4 and the 8-digit clinical trial number. For patients with Medicare participating in the CMS National Patient Registry for monoclonal antibodies directed against amyloid for the treatment of AD, use NCT number 06058234.⁷ If the patient is enrolled in a different CMS-approved CED registry, please use the assigned Clinicaltrials.gov number as appropriate.

FIELD 42 AND 43: REVENUE CODES AND DESCRIPTION

Enter the revenue codes that correspond to HCPCS or CPT® codes outlined in FL 44. Payers may vary on revenue code requirements for each procedure/service performed. Please see page 12 for revenue codes.

FIELD 44: PRODUCT AND PROCEDURE CODING

Enter the HCPCS and CPT code for the administration of Kisunla. Be sure to also enter the appropriate HCPCS modifiers on the same line, including either Q0 or Q1 if the patient is enrolled in a CMS registry.⁵ Note if the full single dose was administered or if any portion was discarded; append the appropriate modifier JW, JZ. Please see page 6 for HCPCS codes, page 8 for CPT codes, and pages 9 and 10 for HCPCS modifiers.

FIELD 46: SERVICE UNITS

Enter the appropriate units for the HCPCS and CPT code. When billing for Kisunla using J0175, 1 unit = 2 mg. Report 125 units (350 mg) for infusion one, 350 units (700 mg) for infusion two, 525 units (1050 mg) for infusion three, and 700 units (1400 mg) for infusion four and beyond.^{3,8} When billing 96413 or 96365 for Kisunla, 1 unit = 1 infusion.

FIELD 67: DIAGNOSIS CODES

Enter the appropriate diagnosis code in lines A-Q to identify the patient’s diagnosis/condition. Use the highest level of specificity. Be sure to also include Z00.6 to denote participation in a clinical research program, as appropriate.⁴ See page 5 for ICD-10-CM codes.

FIELD 80: REMARKS

To support the review and payment of the claim, include additional information as requested by respective payers. Please see page 7 for NDC number and page 9 for registry numbers.

Please see additional [Important Safety Information](#) and full [Prescribing Information](#), including Boxed Warning for ARIA, and [Medication Guide](#) for Kisunla.

All coding and documentation requirements for drugs should be confirmed with each payer.

For more information, please visit www.cms.gov.



**IMPORTANT SAFETY INFORMATION FOR Kisunla™
(donanemab-azbt)**

**WARNING: AMYLOID-RELATED IMAGING
ABNORMALITIES**

Monoclonal antibodies directed against aggregated forms of beta amyloid, including Kisunla, can cause amyloid-related imaging abnormalities (ARIA), characterized as ARIA with edema (ARIA-E) and ARIA with hemosiderin deposition (ARIA-H). ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events can occur. ARIA can be fatal. Serious intracerebral hemorrhages >1 cm, some of which have been fatal, have been observed in patients treated with this class of medications. 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 Kisunla.

ApoE ε4 Homozygotes: Patients treated with this class of medications, including Kisunla, who are apolipoprotein E ε4 (ApoE ε4 homozygotes (approximately 15% of Alzheimer’s disease patients) 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, the risk of ARIA across genotypes and the implications of genetic testing results should be discussed with patients.

Consider the benefit for treating Alzheimer’s disease and risk of ARIA when deciding to treat with Kisunla.

Kisunla is **contraindicated** in patients with known serious hypersensitivity to donanemab-azbt or to any of the excipients. Reactions have included anaphylaxis.

Amyloid-Related Imaging Abnormalities (ARIA)

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. When present, reported symptoms associated with ARIA may include, but are not limited to, headache, confusion, visual changes, dizziness, nausea, and gait difficulty. Focal neurologic deficits may also occur. Symptoms associated with ARIA usually resolve over time.

In Study 1, safety was assessed in patients who received Kisunla Dosing Regimen 1 (n=853) compared to those who received placebo (n=874). In Study 2, the effect of different dosing regimens of Kisunla on ARIA was assessed, including in patients who received Kisunla Dosing Regimen 2 (n=212).

Incidence of ARIA

A lower incidence of ARIA was observed with Dosing Regimen 2 as compared to Dosing Regimen 1. Therefore, Dosing Regimen 2 is the recommended dosage for Kisunla.

In Study 1, symptomatic ARIA-E occurred in 6% of patients through 18 months of treatment with Kisunla. Clinical symptoms associated with ARIA resolved in approximately 85% of those patients.

Including asymptomatic radiographic events, ARIA, ARIA-E, and ARIA-H were observed with Kisunla: 36%, 24%, and 31% of patients treated with Kisunla, respectively compared to 14%, 2%, and 13% of patients on placebo. There was no increase in isolated ARIA-H for Kisunla vs placebo.

In Study 2, symptomatic ARIA-E occurred in 3% of patients and symptomatic ARIA-H occurred in less than 1% of patients through 12 months of treatment with Kisunla. Clinical symptoms associated with ARIA-E resolved in approximately 67% of patients at 12 months. Including asymptomatic radiographic events, ARIA, ARIA-E, and ARIA-H were observed in 29%, 16%, and 25% of patients treated with Kisunla.

Incidence of Intracerebral Hemorrhage (ICH)

ICH >1 cm in diameter was reported in 0.5% of patients treated with Kisunla vs 0.2% on placebo in Study 1 and in 1% of patients treated with Kisunla in Study 2. Fatal events of ICH have been observed in patients taking Kisunla.

Risk Factors for ARIA and ICH

ApoE ε4 Carrier Status

The risk of ARIA, including symptomatic and serious ARIA, is increased in ApoE ε4 homozygotes.

Recommendations for management of ARIA do not differ based on ApoE ε4 carrier status. Testing for ApoE ε4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA. An FDA- authorized test for detection of ApoE ε4 alleles is not currently available. Currently available tests may vary in accuracy and design.

Radiographic Findings of Cerebral Amyloid Angiopathy (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 magnetic resonance imaging (MRI), which may be suggestive of CAA, were identified as risk factors for ARIA. Patients were excluded from enrollment in Study 1 and Study 2 for findings on neuroimaging of prior ICH >1 cm in diameter, >4 microhemorrhages, >1 area of superficial siderosis, severe white matter disease, and vasogenic edema.

Concomitant Antithrombotic or Thrombolytic Medication

In Study 1, baseline use of antithrombotic medication (aspirin, other antiplatelets, or anticoagulants) was allowed. The majority of exposures to antithrombotic medications were to aspirin. The number of events and the limited exposure to non-aspirin antithrombotic medications limit definitive conclusions about the risk of ARIA or ICH in patients taking antithrombotic medications.

One fatal ICH occurred in a patient taking Kisunla in the setting of focal neurologic symptoms of ARIA and the use of a thrombolytic agent in Study 1, and one fatal intracerebral hemorrhage occurred in the setting of ARIA and the use of a thrombolytic agent in Study 2. 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, and additional caution should be exercised when considering the administration of antithrombotics or a thrombolytic agent (eg, tissue plasminogen activator) to a patient being treated with Kisunla. Advise patients to carry information that they are being treated with Kisunla.

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

Monitoring and Dose Management Guidelines

Obtain a recent baseline brain MRI prior to initiating treatment and prior to the 2nd, 3rd, 4th, and 7th infusions. Enhanced clinical vigilance for ARIA is recommended during the first 24 weeks of treatment with Kisunla. 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.

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, interrupt treatment, or permanently discontinue Kisunla. See Prescribing Information for additional dosing considerations.

Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis and angioedema, have occurred in patients who were treated with Kisunla. 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 (IRR)

IRRs were observed with Kisunla with the majority occurring within the first 4 infusions. Most IRRs occurred during the infusion or within 30 minutes after completion of the infusion, however some have occurred hours after an infusion. Signs and symptoms of IRRs include chills, erythema, nausea/vomiting, flushing, difficulty breathing/dyspnea, sweating, elevated blood pressure, headache, chest pain, and low blood pressure.

In the event of an IRR, the infusion rate may be reduced, or the infusion may be discontinued, and appropriate therapy initiated as clinically indicated. Consider pre-treatment with antihistamines, acetaminophen, or corticosteroids prior to subsequent dosing.

Adverse Reactions: The most common adverse reactions reported in ≥5% of patients treated with Kisunla and ≥2% higher than placebo were ARIA-H microhemorrhage, ARIA-E, ARIA-H superficial siderosis, headache, and IRRs.

Kisunla (donanemab-azbt) injection for intravenous use is available as a 350 mg/20 mL single-dose vial.

Please see full [Prescribing Information](#) for Kisunla, including [Boxed Warning](#) regarding ARIA, and [Medication Guide](#).

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LILLY SUPPORT SERVICES FOR KISUNLA OFFERS CUSTOMIZED SUPPORT TO FIT YOUR PATIENT'S NEEDS

Lilly Support Services for Kisunla is a free support program that can partner with your patients to help them stay on track with their treatment and feel supported to



Better understand insurance coverage, complete treatment costs, and saving options



Know what to expect when starting and continuing on Kisunla treatment



Navigate infusion and safety monitoring requirements across sites of care



Access customized support from registered nurses and resources along their treatment journey

For more information, visit <https://kisunla.lilly.com/hcp/support-resources> or call Lilly Support Services at 1-800-LillyRx (1-800-545-5979).

References: 1. CMS.gov. Monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease (CAG-00460N). Accessed February 20, 2024. <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncid=305> 2. CMS.gov. Monoclonal antibodies directed against amyloid for the treatment of Alzheimer's Disease (AD). Accessed February 20, 2024. <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncid=375&ncdver=1> 3. Centers for Medicare & Medicaid Services. National patient registry for new Alzheimer's drugs: things to know for clinicians. Published July 6, 2023. Accessed February 20, 2024. <https://qualitynet.cms.gov/files/64a7151bd15911001c695b32?filename=Provider%20FactSheet%20Alzheimers%20Treatment.pdf> 4. Centers for Disease Control and Prevention. ICD-10-CM tabular list of diseases and injuries (2024). National Center for Health Statistics. Published July 5, 2023. 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Please see [Important Safety Information](#) and full [Prescribing Information](#), including [Boxed Warning for ARIA](#), and [Medication Guide](#) for Kisunla.



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