Lilly
A MEDICINE COMPANY

kisunla™
(donanemab-azbt)
injection for IV infusion
350 mg/20 mL
A Lilly Medicine

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 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. 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 who are apolipoprotein E ε4 (ApoE ε4) 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 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.

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 kisunla.lilly.com/hcp 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)

Kisunla can cause ARIA-E, which can be observed on magnetic resonance imaging (MRI) as brain edema or sulcal effusions, and ARIA-H, which includes microhemorrhage and superficial siderosis. ARIA can occur spontaneously in patients with Alzheimer's disease, particularly in patients with MRI findings suggestive of cerebral amyloid angiopathy, such as pretreatment microhemorrhage or superficial siderosis. ARIA-H generally occurs with ARIA-E. ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events, including seizure and status epilepticus, rarely can occur. 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 addition to ARIA, intracerebral hemorrhages (ICH) >1 cm in diameter have occurred in patients treated with Kisunla.

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

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CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERS KISUNLA UNDER COVERAGE WITH EVIDENCE DEVELOPMENT (CED)[1,2]

NATIONAL COVERAGE DETERMINATION (NCD) ON MONOCLONAL ANTIBODIES DIRECTED AGAINST AMYLOID FOR THE TREATMENT OF ALZHEIMER'S DISEASE (AD) (200.3)

CMS provides coverage for 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[1]:

Coverage criteria—drugs in class that receive traditional FDA approval[1]:

- 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 information[3]:

- **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

- **ApoE ε4 Carrier Status:** The risk of ARIA, including symptomatic and serious ARIA, is increased in apolipoprotein E ε4 (ApoE ε4) homozygotes.
- The recommendations for management of ARIA do not differ between ApoE ε4 carriers and noncarriers. 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 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.	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**			
	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.

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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 350 units (700 mg) for infusions 1, 2, and 3 and 700 units (1400 mg) for infusions 4 and beyond.[3,8] Number of units should be reported in Field 24G of the CMS-1500 Payer Form or Field 46 of the CMS-1450/ UB-04 Form.
	Enter the number of units	Field 24G	Field 46	

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[8]	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[8]	00002-9401-01			

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.
- In Study 1, 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.

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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.
- 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

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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.
- There is limited experience in patients who continued dosing through asymptomatic but radiographically mild to moderate ARIA-E. There are limited data for dosing patients who experienced recurrent episodes of ARIA-E.

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.

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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) Field 43 (description of service)	Revenue code requirements for claims with a CPT® code for IV infusion may vary.
	0636 (Drug requiring detailed coding)		
	0260 (IV therapy—general classification)		
	0262 (IV therapy—IV therapy/pharmacy services)		
	0510 (Clinic—general classification)		

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: 9% (74/853); placebo: 0.5% (4/874); the majority (70%, 52/74) occurred within the first 4 infusions. IRRs typically occur during infusion or within 30 minutes post-infusion. IRRs were mostly mild (57%) or moderate (39%) in severity. Signs and symptoms of IRRs include chills, erythema, nausea/vomiting, 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.

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

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]

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 use[13]:

- 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.

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PHYSICIAN OFFICE AND FREESTANDING INFUSION CENTER

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 350 units (700 mg) for infusions 1, 2, and 3 and 700 units (1400 mg) for infusions 4 and beyond.[3,8] When billing 96413 or 96365 for Kisunla, 1 unit = 1 infusion.

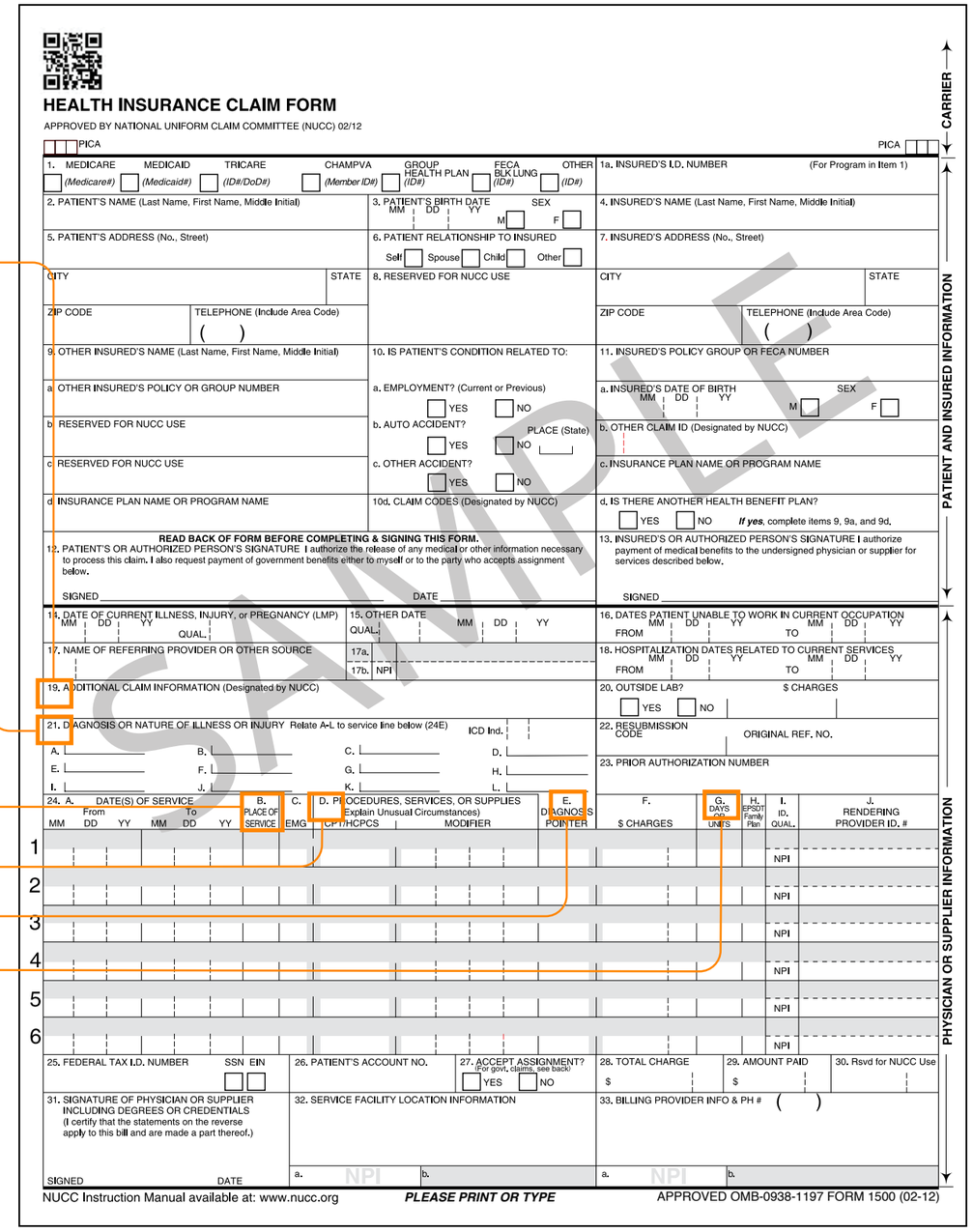
SELECT IMPORTANT SAFETY INFORMATION

Adverse Reactions

The most common adverse reactions reported in ≥5% of patients treated with Kisunla (n=853) and ≥2% higher than placebo (n=874): ARIA-H microhemorrhage (25% vs 11%), ARIA-E (24% vs 2%), ARIA-H superficial siderosis (15% vs 3%), headache (13% vs 10%), and IRRs (9% vs 0.5%).

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
PICA
1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)
1a. INSURED'S I.D. NUMBER (For Program in Item 1)
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)
3. PATIENT'S BIRTH DATE MM DD YY SEX M F
4. INSURED'S NAME (Last Name, First Name, Middle Initial)
5. PATIENT'S ADDRESS (No., Street)
6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other
7. INSURED'S ADDRESS (No., Street)
CITY STATE
8. RESERVED FOR NUCC USE
ZIP CODE TELEPHONE (Include Area Code) ( )
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
a. OTHER INSURED'S POLICY OR GROUP NUMBER
a. EMPLOYMENT? (Current or Previous) YES NO
a. INSURED'S DATE OF BIRTH MM DD YY SEX M F
b. RESERVED FOR NUCC USE
b. AUTO ACCIDENT? PLACE (State) YES NO
b. OTHER CLAIM ID (Designated by NUCC)
c. RESERVED FOR NUCC USE
c. OTHER ACCIDENT? YES NO
c. INSURANCE PLAN NAME OR PROGRAM NAME
d. INSURANCE PLAN NAME OR PROGRAM NAME
10d. CLAIM CODES (Designated by NUCC)
d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO If yes, complete items 9, 9a, and 9d.
READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.
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.
SIGNED DATE
13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.
SIGNED
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.
15. OTHER DATE QUAL. MM DD YY
16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE
17a.
17b. NPI
18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)
20. OUTSIDE LAB? YES NO $ CHARGES
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.
A. B. C. D.
E. F. G. H.
I. J. K. L.
22. RESUBMISSION CODE ORIGINAL REF. NO.
23. PRIOR AUTHORIZATION NUMBER
24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY | B. PLACE OF SERVICE | C. EMG | D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER | E. DIAGNOSIS POINTER | F. $ CHARGES | G. DAYS OR UNITS | H. EPSDT Family Plan | I. ID. QUAL. | J. RENDERING PROVIDER ID. #
1 NPI
2 NPI
3 NPI
4 NPI
5 NPI
6 NPI
25. FEDERAL TAX I.D. NUMBER SSN EIN
26. PATIENT'S ACCOUNT NO.
27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO
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.)
SIGNED DATE
32. SERVICE FACILITY LOCATION INFORMATION
a. NPI b.
33. BILLING PROVIDER INFO & PH # ( )
a. NPI b.
NUCC Instruction Manual available at: www.nucc.org
PLEASE PRINT OR TYPE
APPROVED OMB-0938-1197 FORM 1500 (02-12)
CARRIER
PATIENT AND INSURED INFORMATION
PHYSICIAN OR SUPPLIER INFORMATION

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

kisunla™ (donanemab-azbt) injection for IV infusion 350 mg/20 mL
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HOSPITAL OUTPATIENT

SAMPLE CLAIM FORM (CMS-1450)

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

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 350 units (700 mg) for infusions 1, 2, and 3 and 700 units (1400 mg) for infusions 4 and beyond.[3,8] When billing 96413 or 96365 for Kisunla, 1 unit = 1 infusion.

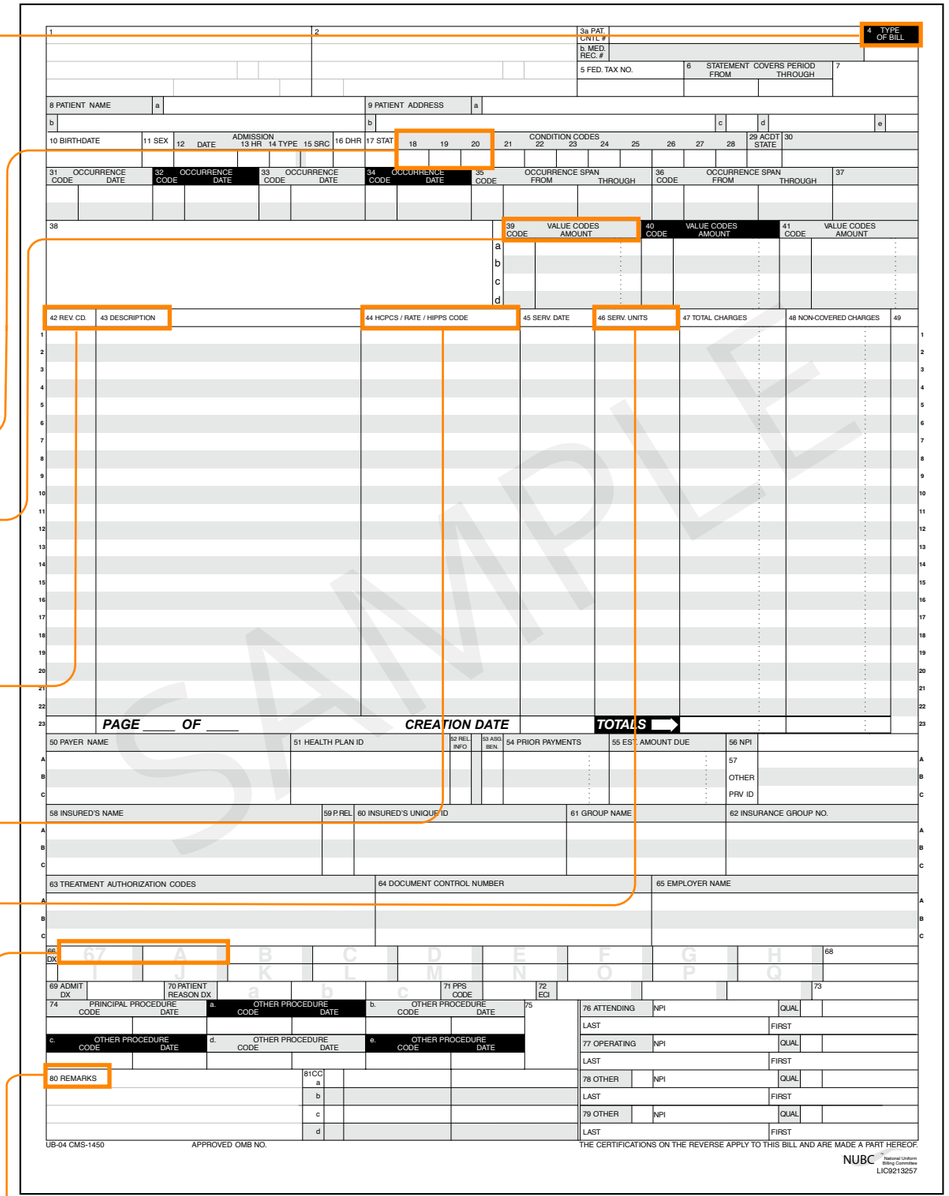
FIELD 67: DIAGNOSIS CODES

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.



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

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

kisunla™ (donanemab-azbt) injection for IV infusion 350 mg/20 mL

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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 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. 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 who are apolipoprotein E ε4 (ApoE ε4) homozygotes (approximately 15% of Alzheimer's disease patients) 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 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 Kisunla; however, it cannot be determined if they are ApoE ε4 homozygotes and at higher risk for ARIA.

Consider the benefit of Kisunla for the treatment of Alzheimer's disease and potential risk of serious adverse events associated with ARIA when deciding to initiate treatment 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)

Kisunla can cause ARIA-E, which can be observed on magnetic resonance imaging (MRI) as brain edema or sulcal effusions, and ARIA-H, which includes microhemorrhage and superficial siderosis. ARIA can occur spontaneously in patients with Alzheimer's disease (AD), particularly in patients with MRI findings suggestive of cerebral amyloid angiopathy, such as pretreatment microhemorrhage or superficial siderosis. ARIA-H generally occurs with ARIA-E.

ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events, including seizure and status epilepticus, rarely can occur. 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 addition to ARIA, intracerebral hemorrhages (ICH) >1 cm in diameter have occurred in patients treated with Kisunla.

Incidence of ARIA

Symptomatic ARIA occurred in 6% (52/853) of patients treated with Kisunla. Clinical symptoms associated with ARIA resolved in approximately 85% (44/52) of patients.

Including asymptomatic radiographic events, ARIA was observed with Kisunla: 36% (307/853); placebo: 14% (122/874). ARIA-E was observed with Kisunla: 24% (201/853); placebo: 2% (17/874). ARIA-H was observed with Kisunla: 31% (263/853); placebo: 13% (111/874). There was no increase in isolated ARIA-H for Kisunla vs placebo.

Incidence of ICH

ICH >1 cm in diameter was reported in 0.5% (4/853) of patients after treatment with Kisunla vs 0.2% (2/874) on placebo. Fatal events of ICH have been observed.

Risk Factors for ARIA and ICH

ApoE ε4 Carrier Status

The risk of ARIA, including symptomatic and serious ARIA, is increased in apolipoprotein E ε4 (ApoE ε4) homozygotes. 17% (143/850) of patients in the Kisunla arm were ApoE ε4 homozygotes, 53% (452/850) were heterozygotes, and 30% (255/850) were noncarriers. The incidence of ARIA was higher in ApoE ε4 homozygotes (Kisunla: 55%; placebo: 22%) than in heterozygotes (Kisunla: 36%; placebo: 13%) and noncarriers (Kisunla: 25%; placebo: 12%). Among patients treated with Kisunla, symptomatic ARIA-E occurred in 8% of ApoE ε4 homozygotes compared with 7% of heterozygotes and 4% of noncarriers. Serious events of ARIA occurred in 3% of ApoE ε4 homozygotes, 2% of heterozygotes, and 1% of noncarriers.

The recommendations for management of ARIA do not differ between ApoE ε4 carriers and noncarriers. 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 MRI, which may be suggestive of CAA, were identified as risk factors for ARIA. Patients were excluded from enrollment in Study 1 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 incidence of ARIA-H was 30% (106/349) in patients taking Kisunla with a concomitant antithrombotic medication within 30 days vs 29% (148/504) in patients who did not receive an antithrombotic within 30 days of an ARIA-H event. The incidence of ICH >1 cm in diameter was 0.6% (2/349) in patients taking Kisunla with a concomitant antithrombotic medication vs 0.4% (2/504) in those who did not receive an antithrombotic. 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. 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.

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. 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.

Radiographic Severity

The majority of ARIA-E radiographic events occurred early in treatment (within the first 24 weeks), although ARIA can occur at any time and patients can have more than one episode. The maximum radiographic severity of ARIA-E in patients treated with Kisunla was mild in 7% (59/853), moderate in 15% (128/853), and severe in 2% (14/853). Resolution on MRI after the first ARIA-E event occurred in 63% of patients treated with Kisunla by 12 weeks, 80% by 20 weeks, and 83% overall after detection. The maximum radiographic severity of ARIA-H microhemorrhage in patients treated with Kisunla was mild in 17% (143/853), moderate in 4% (34/853), and severe in 5% (40/853). The maximum radiographic severity of ARIA-H superficial siderosis in patients treated with Kisunla was mild in 6% (47/853), moderate in 4% (32/853), and severe in 5% (46/853). Among patients treated with Kisunla, the rate of severe radiographic ARIA-E was highest in ApoE ε4 homozygotes 3% (4/143) vs heterozygotes 2% (9/452) or noncarriers 0.4% (1/255). The rate of severe radiographic ARIA-H was highest in ApoE ε4 homozygotes 22% (31/143) vs heterozygotes 8% (38/452) or noncarriers 4% (9/255).

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 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.

There is limited experience in patients who continued dosing through asymptomatic but radiographically mild to moderate ARIA-E. There are limited data for dosing patients who experienced recurrent episodes of ARIA-E.

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: 9% (74/853); placebo: 0.5% (4/874); the majority (70%, 52/74) occurred within the first 4 infusions. IRRs typically occur during infusion or within 30 minutes post-infusion. IRRs were mostly mild (57%) or moderate (39%) in severity. IRRs resulted in discontinuations in 4% (31/853). Signs and symptoms of IRRs include chills, erythema, nausea/vomiting, 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. Pretreatment with antihistamines, acetaminophen, or corticosteroids prior to subsequent dosing may be considered.

Adverse Reactions: The most common adverse reactions reported in ≥5% of patients treated with Kisunla (n=853) and ≥2% higher than placebo (n=874): ARIA-H microhemorrhage (25% vs 11%), ARIA-E (24% vs 2%), ARIA-H superficial siderosis (15% vs 3%), headache (13% vs 10%), IRRs (9% vs 0.5%).

Please see full Prescribing Information, including Boxed Warning regarding ARIA, and Medication Guide.

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LILLY SUPPORT SERVICES™ FOR KISUNLA OFFERS THE CUSTOMIZED SUPPORT YOUR PATIENTS NEED

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

- Better understand insurance coverage, complete treatment costs, and saving options
- Know what to expect when starting on Kisunla and different steps they might expect during 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)**.

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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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