Lilly

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

KISUNLA™ (donanemab-azbt): UNDERSTANDING COST, COVERAGE, AFFORDABILITY, AND SUPPORT

Kisunla is approved for adults with early symptomatic Alzheimer's disease (AD) (mild cognitive impairment [MCI] or mild dementia stage of disease).

SELECT SAFETY INFORMATION

Kisunla can cause **Amyloid-Related Imaging Abnormalities, or "ARIA." ARIA is a common but serious side effect that does not usually cause any symptoms, but can be serious. ARIA can be fatal.** ARIA is most commonly seen as temporary swelling in an area or areas of the brain that usually goes away over time. Some people may also have spots of bleeding on the surface of or in the brain and infrequently, larger areas of bleeding in the brain can occur.

SEE INDICATION AND SAFETY SUMMARY WITH WARNINGS FOR ARIA BELOW FOR ADDITIONAL INFORMATION.

Alzheimer's disease is one of the most common causes of dementia

accounting for an estimated 60% to 80% of cases.[1]

DISEASE PREVALENCE

In 2024, an estimated

6.9 million

Americans aged 65 and older are living with Alzheimer's dementia.[1]

The following data/information is obtained from real-world evidence (RWE) studies.

Real-world evidence differs from evidence derived from clinical trials in terms of study design and methodology, patient population, the way in which treatments are assigned (random vs. non-random), outcomes assessed, and source of data. Results from RWE are not intended for direct comparison to clinical trial results and should be viewed as complementary information.

An estimated 1.3 million individuals in the US have MCI or mild dementia due to AD and evidence of amyloid pathology.[2, 3*] Based on the known rates of underdiagnosis, there may be a gap between the actual prevalence and the currently diagnosed population.[1]

*Population estimates were based on a targeted literature review conducted in April 2022 (initial search) and December 2022 (follow-up search), which identified scientific and gray literature publications based on set criteria. Studies were included if they were English language and US-based; assessed adult patients aged >60 years with Alzheimer's disease, MCI, or dementia; and mentioned one of the following in the title or abstract: prevalence, incidence, morbidity, or population. Studies were excluded if the patients assessed were subgroup data, had certain comorbidities, or had any medical condition other than Alzheimer's disease, and if the studies were one of the following: case series, case-control studies, case reports, clinical trials, book chapters, comments, reviews, letters, notes, or editorials.[2]

Calculations were conducted in a stepwise approach in order to estimate the population in 5-year increments starting at age 60 to 64 up to age 90+. Lower and upper 95% confidence interval values for each prevalence value were used to calculate the lower and upper estimates of the populations of interest. Key limitations include the fact that the stepwise population cascade approach is inherently limited by the fact that each set of inputs was estimated in a different population at different times. Meta-analyses were used when available to reduce bias; more rigorous population studies are warranted, especially for the early symptomatic stages of AD (MCI and mild dementia due to AD).[2]

Cost of Care

Healthcare and long-term costs for people with AD or other dementias are substantial, and **dementia imposes one of the highest financial burdens on society**.[1] Researchers discovered that the total lifetime cost of caring for people with Alzheimer's dementia is more than double the cost of caring for people without the disease, resulting in an estimated lifetime cost of $394,683 in 2023 for people with Alzheimer's dementia.[1]

About Kisunla™

Kisunla (donanemab-azbt) is for adults with early symptomatic AD, which includes MCI or mild dementia stage of disease as well as confirmed amyloid pathology.[4]

Kisunla can reduce excessive amyloid plaques that are associated with early symptomatic AD. Early symptomatic AD can present with memory and thinking issues like forgetting new information, missing important dates and appointments, losing your train of thought, and having difficulty planning or organizing.[1, 4, 5, 6]

IN THE TRAILBLAZER-ALZ 2 PHASE 3 STUDY,

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AFTER 18 MONTHS:

35%

Individuals treated with Kisunla who were less neuropathologically advanced in their disease **showed a significant slowing of decline of 35%** at 18 months compared to placebo.[4, 7]*

22%

Individuals treated with Kisunla in the combined population also **showed a significant slowing of decline of 22%** at 18 months compared to placebo.[4, 7]*

Individuals who were less neuropathologically advanced in their disease had low/medium levels of tau, another protein in the brain associated with AD. The combined population included people with low/medium or high levels of tau. A higher amount of tau is thought to be a factor in determining how far along a person is in the disease progression.[8, 9]

**Measured using the integrated Alzheimer's Disease Rating Scale (iADRS), which measures memory, thinking, and daily functioning.*

IN THE COMBINED POPULATION OF PEOPLE RECEIVING KISUNLA, THE PERCENTAGES OF PATIENTS ELIGIBLE TO SWITCH TO PLACEBO BASED ON AMYLOID LEVELS ON IMAGING WERE:[4]

17% at 6 months

47% at 12 months

69% at 18 months

In the clinical trial, people were able to complete treatment and switch to placebo at 6, 12, or 18 months after they achieved one of the study's treatment goals, minimal levels of amyloid plaque consistent with a visually negative amyloid PET scan. The long-term clinical benefit of Kisunla after stopping treatment has not been studied.[4]

SELECT SAFETY INFORMATION

Kisunla can cause **Amyloid-Related Imaging Abnormalities, or "ARIA"**. Although most people do not have symptoms, some people have headache, dizziness, nausea, difficulty walking, confusion, vision changes, and seizures. **Call your healthcare provider or go to the emergency room right away if you have any of these symptoms**. You should carry information that you are receiving Kisunla, which can cause ARIA, and that ARIA symptoms can look like stroke symptoms.

Some people have a genetic risk factor (homozygous apolipoprotein E ε4 gene carriers) that may cause an increased risk for ARIA. Talk to your healthcare provider about testing to see if you have this risk factor.

You may be at higher risk of developing bleeding in the brain if you take medicines to reduce blood clots from forming while receiving Kisunla. **Talk to your healthcare provider to see if you are on any medicines that increase this risk**.

Your healthcare provider will do magnetic resonance imaging (MRI) brain scans before and during your treatment with Kisunla to check you for ARIA.

See the Indication and Safety Summary with Warnings below for additional information.

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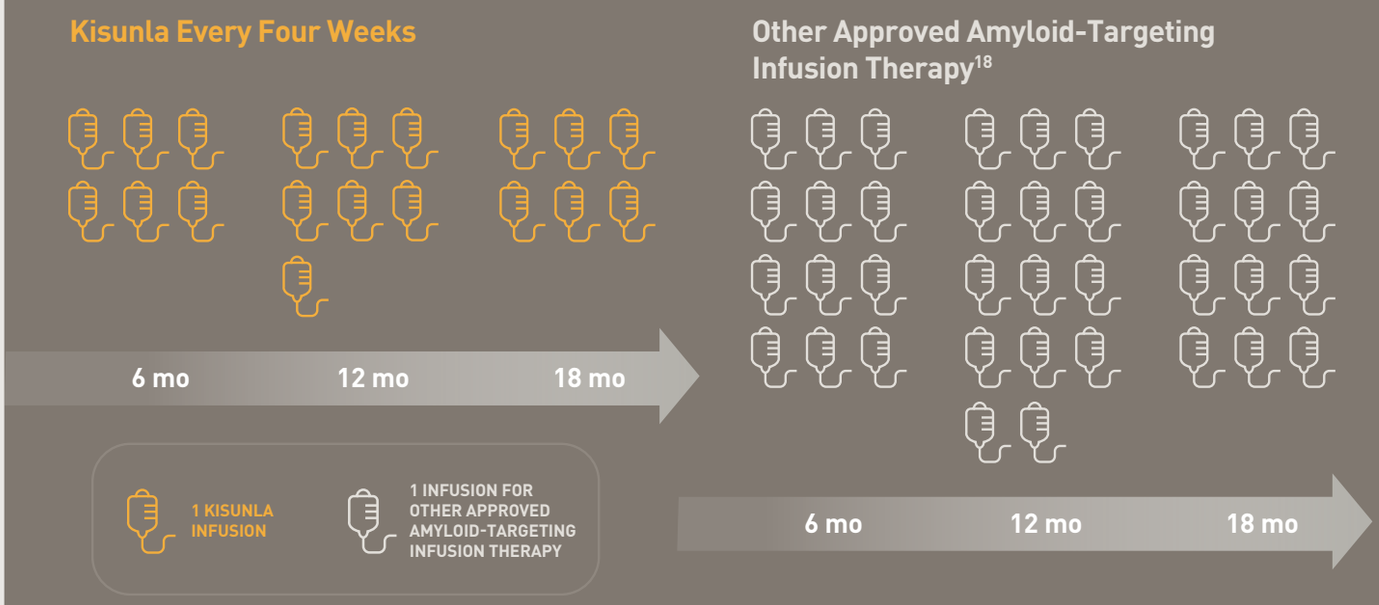
KISUNLA IS A ONCE-MONTHLY TREATMENT,[4] WHICH MAY REDUCE PATIENT INFUSION BURDEN



This graphic portrays only potential maximum dosing regimens per the products' approved labeling and is not intended to compare efficacy or safety.

ONCE-MONTHLY KISUNLA IS THE FIRST AND ONLY FDA-APPROVED AMYLOID-TARGETING THERAPY (ATT) WITH DOSING INSTRUCTIONS THAT ALLOW FOR LIMITED-DURATION TREATMENT.[4*†]

The recommended dosage of Kisunla is 700 mg every 4 weeks for 3 infusions, then 1400 mg every 4 weeks. Kisunla is an IV infusion administered over approximately 30 minutes. Observe the patient for at least 30 minutes after the infusion for infusion-related and hypersensitivity reactions. If an infusion is missed, resume administration every 4 weeks at the scheduled dose as soon as possible. **Consider stopping dosing based on removal of amyloid plaques to minimal levels consistent with a visually negative amyloid positron emission tomography (PET) scan.[4‡]**

In the Phase 3 clinical trial, dosing was stopped in response to observed effects on amyloid imaging. Amyloid PET values may increase after treatment with Kisunla is stopped. There are no data beyond the 76-week duration of TRAILBLAZER-ALZ 2 to guide whether additional dosing with Kisunla may be needed for longer-term clinical benefit.[4]

Obtain recent baseline brain MRI prior to initiating treatment. Perform an MRI prior to infusions 2, 3, 4, and 7. If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including an MRI if indicated. 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.[4] See Prescribing Information for additional dosing considerations.

†In clinical trials, completion of active treatment was based on amyloid PET levels measured at week 24, week 52, and week 76. If amyloid plaque level was <11 Centiloids on a single PET scan or 11 to <25 Centiloids on 2 consecutive PET scans, subjects taking Kisunla were eligible to switch to placebo.[4]

‡For reference, <24.1 Centiloids on an amyloid PET scan is consistent with a negative visual read.[10]

ARIA=amyloid-related imaging abnormalities; ARIA-E=amyloid-related imaging abnormalities-edema; ARIA-H=amyloid-related imaging abnormalities-hemosiderin deposition; ATT=amyloid-targeting therapy; IV=intravenous; MRI=magnetic resonance imaging; PET=positron emission tomography.

TREATMENT DURATION AS WELL AS ONCE-MONTHLY INFUSIONS COULD HAVE IMPLICATIONS FOR PATIENT OUT-OF-POCKET COSTS AND INFUSION BURDEN.

PRICING & COURSE OF CARE COSTS

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The wholesale acquisition cost (WAC) or list price of each vial of Kisunla is $695.65.

The total cost of Kisunla will vary by patient based on length of treatment, as determined by their physicians' clinical judgment.[4]

Based on WAC, the potential course of therapy costs may range from:

Kisunla vial needs based on example treatment duration

Approximate treatment duration scenarios	6 months	12 months	18 months
Number of Kisunla vials	18	46	70
Total cost of Kisunla vials	$12,522	$32,000	$48,696

All costs presented are based solely on the purchase price of medicine, and do not address other services that may be associated with treatment. If you have additional questions about out-of-pocket costs for Kisunla, please contact Lilly Support Services™ for Kisunla at 1-800-LillyRx (1-800-545-5979).

Length of treatment with Kisunla is at the discretion of clinicians.

Recommended dosing per Kisunla Prescribing Information: 700 mg (2 vials) every 28 days for 3 infusions, then 1400 mg (4 vials) every 28 days thereafter.[4]

The cost of therapy can be estimated based on the number of vials per recommended labeling for Kisunla and the WAC of $695.65.

Patients' out-of-pocket cost for treatment with Kisunla will depend on the length of treatment and their insurance.

PATIENT JOURNEY: COVERAGE, AFFORDABILITY, AND SUPPORT

MEDICARE COVERAGE

The following data/information is obtained from real-world evidence (RWE) studies.

According to Lilly-sponsored research from Milliman, we estimate more than 90% of eligible US patients for Kisunla to be on Medicare.[13]* As of 2023, Medicare coverage for amyloid plaque-targeting therapies, including Kisunla, is available through a National Coverage Determination (NCD) with Coverage with Evidence Development (CED),[14] which grants coverage if patients and providers participate in an approved registry. Medicare coverage is also available for amyloid PET scans,[15] which is one diagnostic tool used to help confirm AD pathology.[5]

*The number of people in the US with Medicare coverage and with mild cognitive impairment (MCI) or mild dementia due to Alzheimer's disease (AD) was calculated using published and public research and data.[13]

Calculations were performed using a stepwise approach to estimate the population in 5-year age increments up to age ≥90. Calculations included estimates for the prevalence of clinical symptoms of MCI or dementia, probability of Medicare coverage for people under and over age 65, proportion of dementia that is mild in severity, and the prevalence of amyloid pathology. Key limitations of the study include the reliance on data from various sources representing different points in time, and that the population estimates are likely to include individuals who have not yet been diagnosed or confirmed to be amyloid positive.[13]

Benefits for Medicare beneficiaries are based on the type of plan they choose:

- **TRADITIONAL MEDICARE - FEE FOR SERVICE (FFS)**
  Offered by Medicare, allows patients to purchase supplemental coverage inclusive of Medigap plans that reduce their OOP costs. FFS patients may also qualify for Medicaid or benefit from an employer supplemental plan as part of their retirement.[16]

- **MEDICARE ADVANTAGE (MA)**
  Offered by private insurers, plans must place limits on patient OOP costs. MA patients may also qualify for Medicaid or benefit from an employer supplemental plan as part of their retirement.[16]

The following data/information is obtained from real-world evidence (RWE) studies.

Based on a Lilly-sponsored analysis from Milliman, we expect about 98% of patients with Medicare coverage who are eligible for Kisunla to have some form of coverage that eliminates, limits or caps their OOP exposure for Part B drugs and services.[17]*

*A cross-sectional analysis using the Medicare 100% Research Identifiable Files (RIF) was conducted to characterize Medicare coverage for individuals diagnosed with MCI or AD who were estimated to be potentially eligible for amyloid-targeting therapy. The most recent 3 years of data for Original Medicare (2020-2022) and Medicare Advantage (2018-2020) were used. Population estimates from the latter were extrapolated to 2022 based on Congressional Budget Office projections.[17]

Individuals were included in the coverage analysis if they had an AD or MCI ICD-10 diagnosis code during the analysis period and if they were enrolled in the most recent data year. Individuals were excluded if they had a diagnosis code inconsistent with AD or MCI or if they died, had at least one month of hospice, or were institutionalized during the analysis period. The cohort was further limited by applying a rate of amyloid positivity from the published literature.[17]

Beneficiary coverage (Original Medicare and Medicare Advantage, subset by dual and non-dual) was combined with published information about secondary and supplemental coverages. For each coverage type, Part A and Part B cost sharing assumptions reflect 2023 in-network deductibles, copays, coinsurances, and maximum OOP levels (where applicable) from publicly available sources. A key limitation of the analysis is that the data span years affected by COVID-19. Diagnostic patterns from this period may vary from future experience.[17]

	Insurance Plan	Anticipated OOP Expense
We expect about 98% of patients with Medicare coverage who are eligible for Kisunla to have some form of coverage that eliminates, limits, or caps the amount their OOP exposure for Part B drugs and services.[17]	FFS with VA benefit	Limited to no OOP (based on disability grade)
	FFS with Medicaid	Minimal to no OOP
	FFS with supplemental insurance (Medigap, Employer Sponsored)	Will vary by plan, but intent of these supplements is to address costs not covered by standard part B
	Medicare Advantage Only	20% co-insurance, all protected by maximum out-of-pocket (MOOP), MOOP is $8,300
	Medicare Advantage with Secondary (Medicaid, VA, SNP)	Limited to no OOP
2% of patients with Medicare coverage who are eligible for Kisunla could have no supplemental plans to cap out-of-pockets.[17]	FFS with no supplemental plan(s)	~20%, no MOOP limit

Across FFS and MA, Medicare's cost sharing protections operate to limit total patient OOP expenses associated with covered Alzheimer's care.[17]

COMMERCIAL COVERAGE

We continue to engage payers and employers to encourage adequate commercial coverage for Kisunla and diagnostics with appropriate patient affordability protections.

Eligible commercially insured patients may be eligible for support. Governmental beneficiaries excluded, terms and conditions apply. Please visit **www.kisunla.lilly.com** for additional details.

PATIENT SUPPORT

Lilly Support Services™ for Kisunla is a free support program that partners with patients to help them:

- 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; and,
- Access customized support from registered nurses and resources along their treatment journey.

LILLY'S APPROACH TO VALUE-BASED PRICING

Lilly defines value as the full balance of benefits and costs to patients and society. As detailed in our environmental, social and governance (ESG) report, when making pricing considerations, we use a value-based approach, taking into account the following: customer perspectives; company considerations; competitive landscape; and contributing factors related to health systems.

In the United States, delivering medicines is a shared responsibility across government and commercial payers, pharmacy benefit managers, and other supply chain entities such as wholesalers and distributors.

We are committed to increasing transparency around the price of our medicines and publish list prices for all our medicines.

Learn more about Kisunla by visiting www.Kisunla.Lilly.com.

INDICATION AND SAFETY SUMMARY WITH WARNINGS

Kisunla™ (kih-SUHN-lah) is used to treat adults with early symptomatic Alzheimer's disease (AD), which includes mild cognitive impairment (MCI) or mild dementia stage of disease.

Warnings - Kisunla can cause Amyloid-Related Imaging Abnormalities or "ARIA." This is a common side effect that does not usually cause any symptoms, but serious symptoms can occur. ARIA can be fatal. ARIA is most commonly seen as temporary swelling in an area or areas of the brain that usually goes away over time. Some people may also have spots of bleeding on the surface of or in the brain and infrequently, larger areas of bleeding in the brain can occur. Although most people do not have symptoms, some people have:

- Headache
- Dizziness
- Nausea
- Difficulty walking
- Confusion
- Vision changes
- Seizures

Some people have a genetic risk factor (homozygous apolipoprotein E ε4 gene carriers) that may cause an increased risk for ARIA. Talk to your healthcare provider about testing to see if you have this risk factor.

You may be at higher risk of developing bleeding in the brain if you take medicines to reduce blood clots from forming (antithrombotic medicines) while receiving Kisunla. **Talk to your healthcare provider to see if you are on any medicines that increase this risk.**

Your healthcare provider will do magnetic resonance imaging (MRI) brain scans before and during your treatment with Kisunla to check you for ARIA. You should carry information that you are receiving Kisunla, which can cause ARIA, and that ARIA symptoms can look like stroke symptoms. **Call your healthcare provider or go to the nearest hospital emergency room right away if you have any of the symptoms listed above.**

There are registries that collect information on treatments for Alzheimer's disease. Your healthcare provider can help you become enrolled in these registries.

Warnings - Kisunla can cause serious allergic and infusion-related reactions. Do not receive Kisunla if you have serious allergic reactions to donanemab-azbt or any of the ingredients in Kisunla. Symptoms may include swelling of the face, lips, mouth, or eyelids, problems breathing, hives, chills, irritation of skin, nausea, vomiting, sweating, headache, or chest pain. You will be monitored for at least 30 minutes after you receive Kisunla for any reaction. **Tell your healthcare provider right away if you have these symptoms or any reaction during or after a Kisunla infusion.**

Other common side effects

- Headache

Tell your healthcare provider right away if you have any side effects. These are not all of the possible side effects of Kisunla. **You can report side effects at 1-800-FDA-1088 or www.fda.gov/medwatch.**

Before you receive Kisunla, tell your healthcare provider:

- About all medicines you take, including prescription and over-the-counter medicines, as well as vitamins and herbal supplements. Especially tell your healthcare provider if you have medicines to reduce blood clots from forming (antithrombotic medicines, including aspirin).
- About all of your medical conditions including if you are pregnant, breastfeeding, or plan to become pregnant or breastfeed. Kisunla has not been studied in people who were pregnant or breastfeeding. It is not known if Kisunla could harm your unborn or breastfeeding baby.

How to receive Kisunla

Kisunla is a prescription medicine given through an intravenous (IV) infusion using a needle inserted into a vein in your arm. Kisunla is given once every 4 weeks. Each infusion will last about 30 minutes.

Learn more

For more information about Kisunla, call 1-800-LillyRx (1-800-545-5979) or go to **kisunla.lilly.com**.

This summary provides basic information about Kisunla. It does not include all information known about this medicine. Read the information given to you about Kisunla. This information does not take the place of talking with your healthcare provider. Be sure to talk to your healthcare provider about Kisunla. Your healthcare provider is the best person to help you decide if Kisunla is right for you.

Please see full Prescribing Information including boxed warning for ARIA and Medication Guide for Kisunla.

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