Kisunla™ (donanemab-azbt)
(Intravenous)

Document Number: IC-0763

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I. Length of Authorization

- Coverage will be provided for 6 months and may be renewed annually thereafter.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Kisunla 350 mg/20 mL (17.5 mg/mL) solution in a single-dose vial: 2 vials every 4 weeks for three doses followed by 4 vials every 4 weeks thereafter

B. Max Units (per dose and over time) [HCPCS Unit]:

- 350 billable units every four weeks for the first three doses, followed by 700 billable units every four weeks thereafter.

III. Initial Approval Criteria [1,5,6,9,11]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Physician has assessed baseline disease severity utilizing at least ONE objective measure/tool (i.e., Mini-Mental Status Exam [MMSE], Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog-13/14], Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory-Mild Cognitive Impairment version [ADCS-ADL-MCI], Clinical Dementia Rating-Sum of Boxes [CDR-SB], Montreal Cognitive Assessment (MoCA), etc.); **AND**
- Patient does not have any of the following risk factors for intracerebral hemorrhage: findings suggestive of cerebral amyloid angiopathy (prior cerebral hemorrhage > 1 cm in greatest diameter, > 4 microhemorrhages, superficial siderosis, vasogenic edema); **AND**
- Patients receiving antithrombotic medication (aspirin, other antiplatelets, or anticoagulants) prior to starting treatment with Kisunla have been on a stable dose for at least 4 weeks; **AND**
    - Patient has been tested prior to treatment to assess apolipoprotein E ε4 (ApoE ε4) status (e.g., homozygote, heterozygote, or noncarrier) and the prescriber has informed the patient that those who are homozygotes have a higher incidence of developing ARIA; **OR**
    - Genotype testing has not been performed and the prescriber has informed the patient that it cannot be determined if they are ApoE ε4 homozygotes and, therefore, if they are at higher risk for developing ARIA; **AND**

Universal Criteria [1,5,6,9]

- Must be prescribed by, or in consultation with, a specialist in neurology or gerontology; **AND**
- Patient has received a baseline brain magnetic resonance imaging (MRI) prior to initiating treatment and periodically throughout therapy *(see prescribing information for schedule of MRI scans)*; **AND**
- Patient does not have a clinically significant and unstable psychiatric illness in the past 6 months; **AND**
- Patient does not have a history of alcohol or substance abuse in the preceding year; **AND**
- Will not be used concurrently with other anti-amyloid immunotherapies (i.e., lecanemab, aducanumab, etc.); **AND**

Alzheimer's Disease (AD) † [1,2,5,6,11,12,13]

- Patient has a diagnosis of mild cognitive impairment (MCI) due to AD or has mild Alzheimer's dementia (there is insufficient evidence in moderate or severe AD) AND both of the following:
    - Positron Emission Tomography (PET) scan positive for amyloid beta plaque or CSF assessment positive for hybrid ratios of Aβ 42/40, CSF p-tau 181/Aβ 42, or CSF t-tau/Aβ 42; **AND**
    - One of the following*:
        - Clinical Dementia Rating (CDR)-Global Score of 0.5-1.0 with Memory Box Score of at least 0.5; **OR**
        - MMSE score between 20-28, inclusive; **OR**
        - Montreal Cognitive Assessment (MoCA) score 18-25, inclusive; **AND**
- Other conditions mimicking, but of non-Alzheimer's Dementia etiology, have been ruled out (e.g., vascular dementia, dementia with Lewy bodies [DLB], frontotemporal dementia [FTD], normal pressure hydrocephalus, etc.)

** Note: the aforementioned cognitive tests are typically the most commonly used but do NOT represent an exhaustive list. Use of alternative cognitive assessment tests not listed will be reviewed on a case-by-case basis.*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1,5,6]

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: amyloid related imaging abnormalities-edema (ARIA-E) and -hemosiderin deposition (ARIA-H), intracerebral hemorrhage, severe hypersensitivity reactions including anaphylaxis, etc.; **AND**
- Patient has responded to therapy compared to pretreatment baseline as evidenced by improvement, stability, or slowing in cognitive and/or functional impairment in one or more of the

following (not all-inclusive): ADAS-Cog 13/14; ADCS-ADL-MCI; MMSE; CDR-SB, MoCA, etc.; **AND**

- Patient will discontinue treatment when reduction of amyloid plaques are reduced to minimal levels on amyloid PET imaging, defined as either of the following:
    - Level is <11 Centiloids on a single PET scan; **OR**
    - Level is 11 to <25 Centiloids on two consecutive PET scans; **AND**
- Patient has not progressed to moderate or severe AD; **AND**
- Patient has received a pre- 2nd, 3rd, 4th, AND 7th infusion MRI for monitoring of Amyloid Related Imaging Abnormalities-edema (ARIA-E) and Amyloid Related Imaging Abnormalities-hemosiderin (ARIA-H) microhemorrhages; **AND**

ARIA-E §

- Patient is asymptomatic or mildly symptomatic***** with mild radiographic severity****** on MRI; **OR**
- Patient is asymptomatic or mildly symptomatic***** with moderate to severe radiographic severity****** on MRI AND administration will be suspended until MRI demonstrates radiographic resolution and symptoms, if present, resolve; **OR**
- Patient has moderate to severe symptoms***** with mild to severe radiographic severity****** on MRI AND administration will be suspended until MRI demonstrates radiographic resolution and symptoms, if present, resolve

ARIA-H §

- Patient is asymptomatic with mild radiographic severity****** on MRI; **OR**
- Patient is asymptomatic with moderate radiographic severity****** on MRI AND administration will be suspended until MRI demonstrates radiographic stabilization and symptoms, if present, resolve; **OR**
- Patient is symptomatic with mild to moderate radiographic severity****** on MRI AND administration will be suspended until MRI demonstrates radiographic stabilization and symptoms, if present, resolve; **OR**
- Patient has severe radiographic severity****** on MRI AND administration will be suspended until MRI demonstrates radiographic stabilization and symptoms, if present, resolve

§ *Clinical judgment will be used in considering whether to continue treatment or permanently discontinue. In patients who develop intracerebral hemorrhage greater than 1 cm in diameter during treatment from Kisunla, suspend dosing until MRI demonstrates radiographic stabilization and symptoms, if present, resolve. Consider a follow-up MRI to assess for resolution 2 to 4 months after initial identification.*

Clinical Symptom Severity *		
Mild	**Moderate**	**Severe**
Discomfort noticed, but no disruption of normal daily activity	Discomfort sufficient to reduce or affect normal daily activity	Incapacitating, with inability to work or to perform normal daily activity

ARIA-E	ARIA-E Radiographic Severity**

Symptom Severity [1]	Mild	Moderate	Severe
Asymptomatic	May continue dosing at current dose and schedule	Suspend until MRI demonstrates radiographic resolution and symptoms, if present, resolve; consider a follow-up MRI to assess for resolution 2 to 4 months after initial identification. Resumption of dosing should be guided by clinical judgment.	Suspend until MRI demonstrates radiographic resolution and symptoms, if present, resolve; consider a follow-up MRI to assess for resolution 2 to 4 months after initial identification. Resumption of dosing should be guided by clinical judgment.
Mild	May continue dosing based on clinical judgment		
Moderate or Severe	Suspend until MRI demonstrates radiographic resolution and symptoms, if present, resolve; consider a follow-up MRI to assess for resolution 2 to 4 months after initial identification. Resumption of dosing should be guided by clinical judgment.		

ARIA-H Symptom Severity [1]	ARIA-H Radiographic Severity**		
	Mild	Moderate	Severe
Asymptomatic	May continue dosing at current dose and schedule	Suspend until MRI demonstrates radiographic stabilization and symptoms, if present, resolve; resumption of dosing should be guided by clinical judgment; consider a follow-up MRI to assess for stabilization 2 to 4 months after initial identification	Suspend until MRI demonstrates radiographic stabilization and symptoms, if present, resolve. Use clinical judgment when considering whether to continue treatment or permanently discontinue KISUNLA
Symptomatic	Suspend until MRI demonstrates radiographic stabilization and symptoms, if present, resolve; resumption of dosing should be guided by clinical judgment; consider a follow-up MRI to assess for stabilization 2 to 4 months after initial identification	Suspend until MRI demonstrates radiographic stabilization and symptoms, if present, resolve; resumption of dosing should be guided by clinical judgment; consider a follow-up MRI to assess for stabilization 2 to 4 months after initial identification	

ARIA Type [1]	Radiographic Severity**		
	Mild	Moderate	Severe
ARIA-E	FLAIR hyperintensity confined to sulcus and/or cortex/subcortex white matter in one location < 5 cm	FLAIR hyperintensity 5 to 10 cm in single greatest dimension, or more than 1 site of involvement, each measuring < 10 cm	FLAIR hyperintensity measuring > 10 cm with associated gyral swelling and sulcal effacement. One or more separate/independent sites of involvement may be noted.
ARIA-H microhemorrhage	≤ 4 new incident microhemorrhages	5 to 9 new incident microhemorrhages	10 or more new incident microhemorrhages
ARIA-H superficial siderosis	1 focal area of superficial siderosis	2 focal areas of superficial siderosis	> 2 focal areas of superficial siderosis

V. Dosage/Administration [1]

Indication	Dose
Alzheimer's Disease (AD)	The recommended dosage of Kisunla is 700 mg administered as an intravenous infusion over approximately 30 minutes every four weeks for the first three doses, followed by 1400 mg every four weeks thereafter.
– *Obtain a recent baseline brain magnetic resonance imaging (MRI) prior to initiating treatment with KISUNLA. Obtain an MRI prior to the 2nd, 3rd, 4th, and 7th infusions. If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including an MRI if indicated.* – *If an infusion is missed, resume administration at the same dose as soon as possible.*	

VI. Billing Code/Availability Information

HCPCS Code:

- J0175 – Injection, donanemab-azbt, 2 mg: 1 billable unit = 2 mg

NDC:

- Kisunla 350 mg/20 mL (17.5 mg/mL) solution in a single-dose vial: 00002-9401-xx

VII. References

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G30.0	Alzheimer's disease with early onset
G30.1	Alzheimer's disease with late onset
G30.8	Other Alzheimer's disease
G30.9	Alzheimer's disease, unspecified
G31.84	Mild cognitive impairment of uncertain or unknown etiology

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC