

PA Criteria	Criteria Details						
<b>Covered Uses (FDA approved indication)</b>	Kisunla is an amyloid beta-directed antibody indicated for the treatment of Alzheimer’s disease. Treatment with Kisunla should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in the clinical trials.						
<b>Exclusion Criteria</b>	None.						
<b>Required Medical Information</b>	Medical records supporting the request must be provided, including documentation of registry participation and follow-up.						
<b>Other Criteria</b>	Must follow NCD: Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer’s Disease. <a href="https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&amp;ncaid=305">https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&amp;ncaid=305</a>						
<b>Age Restriction</b>	None.						
<b>Prescriber Restrictions</b>	None.						
<b>Coverage Duration</b>	Six months initial and reauthorization. Dose will be approved according to the FDA- approved labeling or within accepted standards of medical practice.  Patient’s physician must be participating in a registry (attestation required).						
<b>Other Criteria/Information</b>	Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. <table border="1" data-bbox="496 1157 1511 1297"> <thead> <tr> <th>HCPCS</th> <th>Description</th> <th>Billing Units/How Supplied</th> </tr> </thead> <tbody> <tr> <td>J0175</td> <td>Kisunla (donanemab-azbt)</td> <td><b>Billing unit: 2 mg</b>  350 mg/20 mL SDV</td> </tr> </tbody> </table>	HCPCS	Description	Billing Units/How Supplied	J0175	Kisunla (donanemab-azbt)	<b>Billing unit: 2 mg</b>  350 mg/20 mL SDV
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STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	3/26/2025	3/26/2025	Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG)	N/A
Approved	N/A	5/15/2025	Pharmacy & Therapeutics (P&T) Committee	5/15/2025