Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 333.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Kisunla (donanemab-azbt)

Applicable line of business:

Commercial	X	Medicaid	X
Medicare		ACA	X
CHIP	X		

I. Policy:
Kisunla (donanemab-azbt)

II. Purpose/Objective:
To provide a policy of coverage regarding Kisunla (donanemab-azbt)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Kisunla (donanemab-azbt) is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against insoluble N-truncated pyroglutamate amyloid beta. The accumulation of amyloid beta plaques in the brain is a defining pathophysiological feature of Alzheimer's disease. Donanemab-azbt reduces amyloid beta plaques.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

For the Medicare line of business, Kisunla (donanemab-azbt) will be covered consistent with the Centers for Medicare & Medicaid Services (CMS) National Coverage Determination (NCD) 200.3 Monoclonal antibodies directed against amyloid for the treatment of Alzheimer's Disease (AD).

Kisunla (donanemab-azbt) will be considered medically necessary for the Medicaid line of business when ALL of the following criteria are met:

- Medical record documentation that Kisunla is prescribed by or in consultation with a dementia specialist (e.g. neurologist, psychiatrist, geriatric psychiatrist, neuropsychiatrist, geriatrician, or gerontologist) **AND**
- Medical record documentation that the dementia specialist at appropriate intervals (prescribing information states MRI is to be obtained at baseline and prior to the 2nd, 3rd, 4th, and 7th infusion) **AND**
- Medical record documentation of a diagnosis of Mild Cognitive Impairment (MCI) due to Alzheimer's Disease (AD) or mild dementia due to Alzheimer's Disease (AD) [diagnosis codes may include G30, G30.0, G 30.1, G30.8, G 30.9, G31.84] **AND**
- Medical record documentation of no medical or neurological conditions (other than Alzheimer's disease) that might be a significant contributing cause of the beneficiary's cognitive impairment **AND**
- Medical record documentation of no contraindications to Magnetic Resonance Imaging (MRI) (e.g. cardiac pacemaker/defibrillator or ferromagnetic metal implants) **AND**
- Medical record documentation of positron emission tomography (PET) scan positive for brain amyloid plaques OR cerebrospinal fluid (CSF) biomarker testing positive for beta-amyloid plaques (as indicated by reduced amyloid beta 42 [Aβ42] levels OR reduced amyloid beta 42 amyloid beta 40 ratio [Aβ42/Aβ40 ratio] in CSF OR elevated total tau amyloid beta 1-42 ratio [t-tau/Aβ1-42]) OR blood based biomarker testing positive for beta-amyloid plaques (as indicated by reduced amyloid beta 42 amyloid beta 40 ratio [Aβ42/Aβ40 ratio] in plasma OR assays for tau phosphorylated at amino acid 181 (p-tau 181), 217 (p-tau217), or 231 (p-tau231) OR high NfL concentrations OR plasma GFAP) **AND**
- Medical record documentation of at least two (2) of the following:
    - Mini-Mental State Examination (MMSE) score of ≥20 to ≤28
    - Montreal Cognitive Assessment (MoCA) score greater than or equal to 17
    - Clinical Dementia Rating-Global Score (CDR-GS) of 0.5 or 1
    - Clinical Dementia Rating-Sum of Boxes (CDR-SB) score less than or equal to 9
    - Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) score less than or equal to 85 or other similar neuropsychology testing demonstrating minor neurocognitive disorder or mild stage dementia level major neurocognitive disorder, and/or
    - Quick Dementia Rating System (QDRS) score less than or equal to 12 **AND**
- Medical record documentation that the member does not have history of stroke, transient ischemic attack (TIA), or seizures in the past year **AND**
- Medical record documentation that the member does not have a bleeding disorder that is not under adequate control (e.g. a platelet count <50,000 or international normalized ratio [INR] > 1.5) **AND**
- Medical record documentation that the member does not have a presence of ARIA-E (and/or ARIA-H) on the most recent MRI scan (brain edema or sulcal effusions) **AND**
- Do not see significant pathological findings on a pre-treatment MRI:
    - More than 4 microhemorrhages (defined as 10 millimeter [mm] or less at the greatest diameter),
    - A single macrohemorrhage > 10 mm at greatest diameter,
    - An area of superficial siderosis,

    - Evidence of vasogenic edema,
    - Evidence of cerebral contusion, encephalomalacia, aneurysms, vascular malformations, or infective lesions,
    - Evidence of multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease,
    - Space occupying lesions, and
    - Brain tumors (excludes lesions diagnosed as meningiomas or arachnoid cysts and less than 1 cm at their greatest diameter) **AND**
- Medical record documentation of a dose that is consistent with FDA-approved package labeling

AUTHORIZATION DURATION: Approval will be given for an initial duration of twelve (12) months or less if the reviewing provider feels it is medically appropriate. After the initial approval, subsequent approvals will be for a duration of twelve (12) months or less if the reviewing provider feels it is medically appropriate, and will require:

- Provider attestation that Kisunla is still medically necessary to continue **AND**
- Medical record documentation that the member is tolerating Kisunla **AND**
- Medical record documentation Kisunla is prescribed by or in consultation with a dementia specialist (e.g. neurologist, psychiatrist, geriatric psychiatrist, neuropsychiatrist, geriatrician, or gerontologist) **AND**
- Medical record documentation that the member was, and will continue to be monitored and assessed by the prescribing dementia specialist at appropriate intervals **AND**
- Medical documentation of no medical or neurological conditions (other than Alzheimer's disease) that might be a significant contributing cause of the beneficiary's cognitive impairment **AND**
- Medical record documentation of no contraindications to Magnetic Resonance Imaging (MRI) (e.g. cardiac pacemaker/defibrillator or ferromagnetic metal implants) **AND**
- Medical record documentation of repeat testing AND documented results of at least two of the following:
    - Mini-Mental State Examination (MMSE),
    - Montreal Cognitive Assessment (MoCA),
    - Clinical Dementia Rating-Global Score (CDR-GS),
    - Clinical Dementia Rating-Sum of Boxes (CDR-SB),
    - Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) OR other similar neuropsychology testing and/or,
    - Quick Dementia Rating System (QDRS)

AND

- One of the following:
    - Medical record documentation that the member does not have history of stroke, transient ischemic attack (TIA), or seizures in the past year OR
    - Medical record documentation of rationale for use in members that have a history of stroke, transient ischemic attack (TIA), or seizures in the past year **AND**
- Medical record documentation that the member does not have a bleeding disorder that is not under adequate control (e.g. a platelet count <50,000 or international normalized ratio [INR] > 1.5) **AND**
- Medical record documentation that the member does not have a presence of ARIA-E (and/or ARIA-H) on the most recent MRI scan (brain edema or sulcal effusions) **AND**
- Do not see significant pathological findings on a recent MRI:
    - More than 4 microhemorrhages (defined as 10 millimeter [mm] or less at the greatest diameter),
    - A single macrohemorrhage > 10 mm at greatest diameter,
    - An area of superficial siderosis,
    - Evidence of vasogenic edema,
    - Evidence of cerebral contusion, encephalomalacia, aneurysms, vascular malformations, or infective lesions,
    - Evidence of multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease,
    - Space occupying lesions, and
    - Brain tumors (excludes lesions diagnosed as meningiomas or arachnoid cysts and less than 1 cm at their greatest diameter) **AND**
- Medical record documentation of a dose that is consistent with FDA-approved package labeling

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

Kisunla (donanemab-azbt) will be considered medically necessary for the commercial, exchange, and CHIP lines of business when ALL of the following criteria are met:

- Medical record documentation of enrollment in a prospective comparative study and/or a registry that collects information regarding treatment with Kisunla **AND**
- Medical record documentation that Kisunla is prescribed by or in consultation with a dementia specialist (e.g. neurologist, psychiatrist, geriatric psychiatrist, neuropsychiatrist, geriatrician, or gerontologist) **AND**
- Medical record documentation that the dementia specialist will monitor the beneficiary at appropriate intervals (prescribing information states MRI is to be obtained at baseline and prior to the 2nd, 3rd, 4th, and 7th infusion) **AND**
- Medical record documentation of a diagnosis of Mild Cognitive Impairment (MCI) due to Alzheimer's Disease (AD) or mild dementia due to Alzheimer's Disease (AD) [diagnosis codes may include G30, G30.0, G 30.1, G30.8, G 30.9, G31.84] **AND**
- Medical record documentation of no medical or neurological conditions (other than Alzheimer's disease) that might be a significant contributing cause of the beneficiary's cognitive impairment **AND**
- Medical record documentation of no contraindications to Magnetic Resonance Imaging (MRI) (e.g. cardiac pacemaker/defibrillator or ferromagnetic metal implants) **AND**
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    - Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) score less than or equal to 85 OR other similar neuropsychology testing demonstrating minor neurocognitive disorder or mild stage dementia level major neurocognitive disorder and/or
    - Quick Dementia Rating System (QDRS) score less than or equal to 12 **AND**
- Medical record documentation that the member does not have history of stroke, transient ischemic attack (TIA), or seizures in the past year **AND**
- Medical record documentation that the member does not have a bleeding disorder that is not under adequate control (e.g. a platelet count <50,000 or international normalized ratio [INR] > 1.5) **AND**
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- Do not see significant pathological findings on a pre-treatment MRI:
    - More than 4 microhemorrhages (defined as 10 millimeter [mm] or less at the greatest diameter),
    - A single macrohemorrhage > 10 mm at greatest diameter,
    - An area of superficial siderosis,
    - Evidence of vasogenic edema,
    - Evidence of cerebral contusion, encephalomalacia, aneurysms, vascular malformations, or infective lesions,
    - Evidence of multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease,
    - Space occupying lesions, and
    - Brain tumors (excludes lesions diagnosed as meningiomas or arachnoid cysts and less than 1 cm at their greatest diameter) **AND**
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- Provider attestation that Kisunla is still medically necessary to continue **AND**
- Medical record documentation that the member is tolerating Kisunla **AND**
- Medical record documentation of continued enrollment in a prospective comparative study and/or a registry that collects information regarding treatment with Kisunla **AND**

- Medical record documentation Kisunla is prescribed by or in consultation with a dementia specialist (e.g. neurologist, psychiatrist, geriatric psychiatrist, neuropsychiatrist, geriatrician, or gerontologist) **AND**
- Medical record documentation that the member was, and will continue to be monitored and assessed by the prescribing dementia specialist at appropriate intervals **AND**
- Medical documentation of no medical or neurological conditions (other than Alzheimer's disease) that might be a significant contributing cause of the beneficiary's cognitive impairment **AND**
- Medical record documentation of no contraindications to Magnetic Resonance Imaging (MRI) (e.g. cardiac pacemaker/defibrillator or ferromagnetic metal implants) **AND**
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    - Mini-Mental State Examination (MMSE),
    - Montreal Cognitive Assessment (MoCA),
    - Clinical Dementia Rating-Global Score (CDR-GS),
    - Clinical Dementia Rating-Sum of Boxes (CDR-SB),
    - Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) OR other similar neuropsychology testing and/or,
    - Quick Dementia Rating System (QDRS)

AND

- One of the following:
    - Medical record documentation that the member does not have history of stroke, transient ischemic attack (TIA), or seizures in the past year OR
    - Medical record documentation of rationale for use in members that have a history of stroke, transient ischemic attack (TIA), or seizures in the past year **AND**
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    - Evidence of multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease,
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    - Brain tumors (excludes lesions diagnosed as meningiomas or arachnoid cysts and less than 1 cm at their greatest diameter) **AND**
- Medical record documentation of a dose that is consistent with FDA-approved package labeling

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 12/19/24

Revised:

Reviewed:

DHS PARP approval: 2/21/25