Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 288.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Leqembi (lecanemab-irmb)

I. Policy:
Leqembi (lecanemab-irmb)

II. Purpose/Objective:
To provide a policy of coverage regarding Leqembi (lecanemab-irmb)

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
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. 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:
Leqembi (lecanemab-irmb) is a humanized monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid beta. Lecanemab reduces amyloid beta plaques, the accumulation of which is a defining pathophysiological feature of Alzheimer disease.

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

For the Medicare line of business, Leqembi (lecanemab-irmb) 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).

Leqembi (lecanemab-irmb) will be considered medically necessary for the Medicaid line of business when ALL of the following criteria are met:

- Medical record documentation that Leqembi (lecanemab-irmb) 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 prior to the 5th, 7th, and 14th infusions) **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, G30.1, G30.8, G30.9, 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 MRI obtained within one year prior to initiating treatment with Leqembi (lecanemab-irmb) **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]) **AND**
- Medical record documentation of <u>at least two (2)</u> of the following:
    - Mini-Mental State Examination (MMSE) score of greater than or equal to 22,
    - 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, and/or
    - Quick Dementia Rating System (QDRS) score less than or equal to 12

  AND
- Medical record documentation that member does not have any exclusions to treatment with Leqembi (lecanemab-irmb), including <u>all</u> of the following:
    - A history of stroke, transient ischemic attack (TIA), or seizures in the past year **AND**
    - A bleeding disorder that is not under adequate control (e.g. a platelet count <50,000 or international normalized ratio [INR] >1.5) **AND**
    - A brain MRI at screening showing <u>any</u> of the following significant pathological findings:
        - 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 twelve (12) month 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:

- Medical record documentation that member continues to experience medical benefit from and tolerability to Leqembi (lecanemab-irmb) based on the prescriber's assessment **AND**
- Medical record documentation Leqembi (lecanemab-irmb) 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 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 continuing treatment with Leqembi (lecanemab-irmb) based on recent MRI results as recommended in the FDA-approved package labeling (e.g. MRI to be obtained prior to the 5th, 7th, and 14th infusions) **AND**
- Medical record documentation of repeat testing AND documented results of <u>at least two</u> 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), and/or
    - Quick Dementia Rating System (QDRS)

  AND
- Medical record documentation that member does not have any exclusions to treatment with Leqembi (lecanemab-irmb), including <u>all</u> of the following:
    - A history of stroke, transient ischemic attack (TIA), or seizures in the past year **AND**
    - A bleeding disorder that is not under adequate control (e.g. a platelet count <50,000 or international normalized ration [INR] >1.5) **AND**
    - A brain MRI at screening showing <u>any</u> of the following significant pathological findings:
        - 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.

<u>Note</u>: 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.

Leqembi (lecanemab-irmb) 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 Leqembi, which can include, but is not limited to, the Alzheimer's Network for Treatment and Diagnostics (ALZ-NET) **AND**
- Medical record documentation Leqembi (lecanemab-irmb) 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 prior to the 5th, 7th, and 14th infusions) **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, G30.1, G30.8, G30.9, 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 MRI obtained within one year prior to initiating treatment with Leqembi (lecanemab-irmb) **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]) **AND**
- Medical record documentation of at least two (2) of the following:
    - Mini-Mental State Examination (MMSE) score of greater than or equal to 22,
    - 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, and/or
    - Quick Dementia Rating System (QDRS) score less than or equal to 12

  AND
- Medical record documentation that member does not have any exclusions to treatment with Leqembi (lecanemab-irmb), including all of the following:
    - A history of stroke, transient ischemic attack (TIA), or seizures in the past year **AND**
    - A bleeding disorder that is not under adequate control (e.g. a platelet count <50,000 or international normalized ratio [INR] >1.5) **AND**
    - A brain MRI at screening showing any of the following significant pathological findings:
        - 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 twelve (12) month 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:

- Medical record documentation that member continues to experience medical benefit from and tolerability to Leqembi (lecanemab-irmb) based on the prescriber's assessment **AND**
- Medical record documentation of continued enrollment in a prospective comparative study and/or a registry that collects information regarding treatment with Leqembi, which can include, but is not limited to, the Alzheimer's Network for Treatment and Diagnostics (ALZ-NET) **AND**

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- 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 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 continuing treatment with Leqembi (lecanemab-irmb) based on recent MRI results as recommended in the FDA-approved package labeling (e.g. MRI to be obtained prior to the 5th, 7th, and 14th infusions) **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), and/or
    - Quick Dementia Rating System (QDRS)

  AND
- Medical record documentation that member does not have any exclusions to treatment with Leqembi (lecanemab-irmb), including all of the following:
    - A history of stroke, transient ischemic attack (TIA), or seizures in the past year **AND**
    - A bleeding disorder that is not under adequate control (e.g. a platelet count <50,000 or international normalized ration [INR] >1.5) **AND**
    - A brain MRI at screening showing any of the following significant pathological findings:
        - 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.

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: 5/16/23

Revised: 9/19/23 (comm/exch/CHIP coverage criteria, Medicaid MRI and amyloid plaque requirements)

Reviewed: