Medicare Advantage Plans

Part B Prior Authorization Criteria

2024

This prior authorization document was updated on 01/04/2024. To determine if your drug has a prior authorization requirement, or for information on how to request an authorization for any of these drugs, please contact Customer Care at 1-844-280-5555 toll free (TTY users should call 711), from 8 am to 8 pm, 7 days a week.

For drugs not listed below, GlobalHealth applies Local Coverage Determination (LCD) or National Coverage Determination (NCD) criteria if available. If LCD or NCD criteria are not available, then FDA-approved indications or medically accepted indications are applied.

Este documento de autorización previa fue actualizado el 01/04/2024. Para determinar si su medicamento tiene un requisito de autorización previa, o para obtener información sobre cómo solicitar una autorización para cualquiera de estos medicamentos, comuníquese con Atención al Cliente al número gratuito 1-844-280-5555 (los usuarios de TTY deben llamar al 711), de 8 a. m. a 8 p. m., los 7 días de la semana.

Para los medicamentos que no se enumeran a continuación, GlobalHealth aplica los criterios de Determinación de Cobertura Local (LCD) o Determinación de Cobertura Nacional (NCD) si están disponibles. Si no se dispone de criterios de LCD o de ENT, se aplican las indicaciones aprobadas por la FDA o las indicaciones médicamente aceptadas.

Pharmacy Utilization Management Policy

	ENTITY GlobalHealth Holdings, LLC	NUMBER GH-PT-096-CM-V-2	
GlobalHealth	TITLE Givlaari Prior Authorization Approval Criteria	EFFECTIVE DATE 1/27/2021	LAST REVISED 4/27/2022

Therapeutic class: Gastrointestinal Agent

Available dosage forms: Subcutaneous Solution: 189 MG/1 ML

Criteria for initial approval (3 months):

1. FDA-approved diagnosis: Acute Hepatic Porphyria (Acute Intermittent Porphyria, Hereditary Corproporhyria, Variegate Porphyria, ALA dehydratase deficient porphyria)
2. Prescribed dose is no more than 2.5mg/kg once monthly
3. Diagnosis is confirmed by genetic testing (applies to Medicare Advantage patients only)
4. Prescribed by or in consultation with a physician who specializes in treatment of Acute Hepatic Porphyria (hepatologist, gastroenterologist, hematologist)
5. Member is 18 years of age or older
6. No anticipated liver transplantation
7. No active HIV, hepatitis C virus, or hepatitis B virus infection(s)
8. No history of recurrent pancreatitis
9. All of the following:
    9.1. Member has elevated urinary or plasma PBG (urinary porphobilinogen) or ALA (urinary aminolevulinic acid) values within the past year; AND
    9.2. Member has active disease, with at least 2 documented porphyria attacks (requiring hospitalization, urgent healthcare visit, or intravenous hemin administration) within the last 6 months; AND
    9.3. Member is not prophylactically using hemin while on the requested treatment (this does NOT include hemin treatment for acute attacks)

Criteria for renewal:

1. Member continues to meet initial approval criteria; AND
2. Member has a positive response, defined as ≥ 70% reduction from baseline in fewer porphyria attacks that required hospitalizations, urgent healthcare visits or intravenous hemin administration; AND
3. No unacceptable toxicity, such as anaphylactic reactions, hepatic toxicity (severe or clinically significant transaminase elevations), renal toxicity, etc.

Medicare Coverage:

There is no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for jurisdiction JL specifically for this drug. Per Local Coverage Article A53127 Self-Administered Drug Exclusion List, Medicare covers drugs that are furnished “incident to” a physician’s service provided that the drugs are medically reasonable and necessary, approved by the Food and Drug Administration (FDA) and are not usually administered by the patients who take them. Therefore, Givosiran (Givlaari) will be covered for Medicare Advantage members when the above utilization management criteria are met AND the drug is furnished and administered by a licensed medical provider as part of a physician service.

References:

1. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically
2. Givlaari [Prescribing Information]. Alnylam Pharmaceuticals, Inc., Cambridge, MA. January 2022. Available at: https://www.alnylam.com/sites/default/files/pdfs/GIVLAARI-Prescribing-Information.pdf
3. ENVISION: A Study to Evaluate the Efficacy and Safety of Givosiran (ALN-AS1) in Patients With Acute Hepatic Porphyrias (AHP). Available at: https://clinicaltrials.gov/ct2/show/NCT03338816

P&T Committee review dates: 1/27/2021, 4/27/2022, 4/26/2023
UM Committee review dates: 12/29/2023

Pharmacy Utilization Management Policy

	ENTITY GlobalHealth Holdings, LLC	NUMBER GH-PT-099-CM-V-1	
GlobalHealth	TITLE Leqembi Prior Authorization Approval Criteria	EFFECTIVE DATE 8/1/2023	LAST REVISED

Therapeutic class: Central Nervous System Agent | Monoclonal Antibody

Available dosage forms: Intravenous Solution: 100 MG/1 ML

Criteria for initial approval:

1. FDA-approved diagnosis: treatment of Alzheimer's disease in patients with mild cognitive impairment or mild dementia stage of disease
2. Documented evidence of beta-amyloid plaque on the brain demonstrated by recent baseline PET/MRI (within the previous 12 months)
3. Prescribed dose is no more than 10 mg/kg once every two weeks.
4. Member is treated by a physician who participates in a qualifying registry with an appropriate clinical team and follow-up care.

Criteria for renewal:

1. Member continues to meet initial approval criteria
2. Member has a positive response to treatment as documented by repeat PET/MRI (months 12 and 18) and assessment by treating physician
3. No unacceptable toxicity is present

Medicare Coverage:

There is no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for jurisdiction JL specifically for this drug. Per Local Coverage Article A53127 Self-Administered Drug Exclusion List, Medicare covers drugs that are furnished "incident to" a physician's service provided that the drugs are medically reasonable and necessary, approved by the Food and Drug Administration (FDA) and are not usually administered by the patients who take them. Therefore, lecanemab (Leqembi) will be covered for Medicare Advantage members when the above utilization management criteria are met AND the drug is furnished and administered by a licensed medical provider as part of a physician service.

References:

1. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically
2. Leqembi [Prescribing Information]. Eisai Inc., Nutley, NJ. July 2023. Available at: https://www.leqembi.com/-/media/Files/Leqembi/Prescribing-Information.pdf?hash=77aa4a86-b786-457a-b894-01de37199024

P&T Committee review dates: 8/1/2023
UM Committee review dates: 12/29/2023