Fee-For-Service (FFS) Physician Administered Drug List

Prior Authorization Criteria

March 2026

Table of Contents

Special Notes:

This criteria only applies to the FFS member outpatient medical benefit.

FFS members must meet the criteria for use for payment of therapy. Please reference the FFS PAD List for procedure codes

Criteria may differ for members covered by a managed care organization. Please contact the respective MCO.

KENTUCKY MEDICAID FEE-FOR-SERVICE
PHYSICIAN ADMINISTERED PRIOR AUTHORIZATION CRITERIA

ADUHELM (aducanumab)

(Only this criteria applies to MCO and FFS members.)

FDA Approved Indication(s)

Treatment with Aduhelm should be initiated in patients with mild cognitive impairment or mild dementia stage (Alzheimer's Disease (AD), which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied. This indication is approved under accelerated approval based on the reduction in amyloid beta plaques observed in patients treated with Aduhelm. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s). This drug was discontinued by the manufacturer.

Policy/Criteria

I. Initial Approval

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. Initial approval is for 6 months.

- Prescribed by or in consultation with a Neurologist, Geriatrician, Geropsychiatric specialist OR AD Specialist. If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests**; and**

- Provider attestation that the member has a diagnosis of mild cognitive impairment (MCI) due to AD or mild dementia associated with AD disease dementia**; and**

- Confirmation of beta-amyloid plaques verified by one of the following
  - Positron emission tomography (PET) scan**; or**
  - Lumbar puncture for cerebrospinal fluid (CSF) testing**; and**

- Prescriber has assessed and documented baseline disease severity utilizing one of the following scores (within the past 6 months):
  - Mini-Mental Status Exam (MMSE) score ≥ 24**; or**
  - Montreal Cognitive Assessment (MoCA) ≥ 15**; and**

- Documentation the member has concurrent or historic trial and failure of 2 or more of the following: Alzheimer's drug therapies [Donepezil (Aricept), Galantamine (Razadyne), Rivastigmine (Exelon)]**; and**

- Documentation within medical record member does not have ANY of the following:
  - Member does NOT have any medical or neurological condition (other than Alzheimer's Disease) that might be a contributing cause of the subject's cognitive impairment, specifically ruling out ALL of the following:
    - vascular dementia**; and**

- Lewy body dementia**; and**
- frontotemporal dementia**; and**
- dementia in down's syndrome**; and**
- Parkinson's disease dementia**; and**

- Member has NOT had a Transient Ischemic Attack (TIA), stroke or unexplained loss of consciousness in the past 1 year**; and**

- Member does NOT have a history or known seropositivity for human immunodeficiency virus (HIV).**; and**

- Member does NOT have any of the following neurological or psychiatric conditions:
  - uncontrolled seizure disorder**; and**
  - uncontrolled mood disorder, anxiety disorder, or psychosis**; and**

- Provider attests that a review of medications (within the past 30 days) is not contributing substantially to cognitive impairment (see Beer's list); **and**

- Member does NOT have any of the following cardiovascular conditions:
  - uncontrolled hypertension**; and**
  - coronary artery disease, including unstable angina and myocardial infarction**; and**
  - heart failure**; and**
  - arrhythmia**; and**
  - clinically significant carotid atherosclerosis and/or peripheral arterial disease**; and**

- Member does NOT have any contraindications to brain magnetic resonance imaging (MRI) or PET scans**; and**

- Member does NOT have any significant cerebrovascular disease as established by brain MRI showing any of the following (within the past year prior to starting treatment):
  - acute or sub-acute hemorrhage**; and**
  - prior macro-hemorrhage or prior subarachnoid underlying structural or vascular hemorrhage**; and**
  - greater than four microhemorrhages**; and**
  - cortical infarct**; and**
  - greater than one lacunar infarct**; and**
  - superficial siderosis**; and**
  - history of diffuse white matter disease**; and**

- Member is NOT currently taking blood thinners (except for aspirin at a prophylactic dose < 325mg/day)**; and**

- Member NOT have any uncontrolled clinically significant chronic medical conditions (e.g. liver disease, kidney disease, pulmonary disease, autoimmune disease requiring

chronic immunosuppression, malignant neoplasm, active chronic infection [HCV], poorly controlled diabetes mellitus).**; and**

- Member does NOT have a recent history (within last year) of the following:
  - use of illicit narcotic medication**; and**
  - alcohol or substance use disorder**; and**

- Prescriber attests to the following:

  - Dose will not exceed the following (must meet all):
    - Infusion 1 and 2: 1 mg/kg per 4 weeks
    - Infusion 3 and 4: 3 mg/kg per 4 weeks
    - Infusion 5 and 6: 6 mg/kg per 4 weeks

  - Follow-up MRI will be obtained at the following time frame:
    - Week 14 (after 4th infusion, prior to the first 6 mg/kg dose)**; and**
    - Week 22 (after 6th infusion, prior to first 10 mg/kg dose)**; and**
    - Week 30 (after 8th infusion, prior to third 10 mg/kg dose)**; and**
    - Week 42 (after 11th infusion; prior to sixths 10 mg/kg dose)**; and**
    - Every six months thereafter**; and**

  - Member and/or authorized representative (e.g., power of attorney, invoked health care proxy) has been informed of the known and potential risks and lack of established clinical benefit associated with Aduhelm treatment.

II. Continuation of Therapy:

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. Continuation of approval is for 1 year.

- Documentation member is able to tolerate the 10mg/kg dosing.**; and**

- Documentation of a follow-up MRI:
  - Week 14 (after 4th infusion, prior to the first 6 mg/kg dose)**; and**
  - Week 22 (after 6th infusion, prior to first 10 mg/kg dose)**; and**
  - Week 30 (after 8th infusion, prior to third 10 mg/kg dose)**; and**
  - Week 42 (after 11th infusion; prior to sixths 10 mg/kg dose)**; and**
  - Every six months thereafter**; and**

- Evaluation for amyloid-related imaging abnormalities and provider documentation clearly indicates which of the following from each category applies to the member:

  - Amyloid-related imaging abnormalities-hemosiderin (ARIA-H), microhemorrhages:
    - Member has no new incident microhemorrhage**; or**
    - Member has had one to four new incident microhemorrhage(s)**; and** and microhemorrhages are asymptomatic (no clinical symptoms)**; or**

- Member has had five to nine new incident microhemorrhage(s)**; and** microhemorrhages are asymptomatic (no clinical symptoms) and the microhemorrhages have been stabilized**; or**
- Member has had one to nine new incident microhemorrhage(s) and microhemorrhages, which have resulted in mild, moderate or severe clinical symptoms and the microhemorrhages have been stabilized**; and**

  - Amyloid-related imaging abnormalities (ARIA-H), superficial siderosis
    - Member has no new incident areas of superficial siderosis**; or**
    - Member has had one new incident area of superficial siderosis and superficial siderosis is asymptomatic (no clinical symptoms)**; or**
    - Member has had two new incident areas of superficial siderosis and superficial siderosis is asymptomatic (no clinical symptoms) and the superficial siderosis has been stabilized**; or**
    - Member has had one to two new incident areas of superficial siderosis, which resulted in mild, moderate or severe clinical symptoms and the superficial siderosis have been stabilized**; and**

  - Amyloid-related imaging abnormalities-edema (ARIA-E)
    - Member has no new ARIA-E**; or**
    - Member has mild ARIA-E on MRI and ARIA-E is asymptomatic (no clinical symptoms)**; or**
    - Member has moderate or severe ARIA-E on MRI and ARIA-E is asymptomatic (no clinical symptoms) and the ARIA-E is stable**; or**
    - Member has had one to two new incident areas of superficial siderosis, which resulted in mild, moderate or severe clinical symptoms and the superficial siderosis have been stabilized.**; and**

- Provider attests that the member does not have an emergence of any of the below-listed conditions OR provides clinical rationale for continued use of Aduhelm with the noted change in clinical status:

  - Member has not developed any of the following conditions:
    - Initiation of anticoagulation**; and**
    - Development of an active immune medicated/autoimmune condition (e.g., Crohn's disease, myasthenia gravis, aplastic anemia, meningitis/encephalitis)**; and**
    - Initiation of immunomodulatory medication (e.g., cancer immunotherapies, rituximab, azathioprine)**; and**
    - Development of other neurologic condition (e.g. intracerebral bleeds, traumatic injury, stroke)**; or**

- A copy of the MMSE or MoCA (within three months of renewal) documenting the member has not had disease progression by one of the following:
  - MMSE $\geq$ 24**; or**
  - MoCA $\geq$ 15**; or**
  - MMSE < 24 or MoCA < 15**; and**
  - Rate of decline was slower than expected (< two points/year)

REFERENCES

1.Aduhelm (aducanumab) [prescribing information]. Cambridge, MA: Biogen Inc; January 2022.

2. Ballard C, Gauthier S, Corbett A, Brayne C, Aarsland D, Jones E. Alzheimer's disease. Lancet. 2011 Mar 19;377(9770):1019-31. doi: 10.1016/S0140-6736(10)61349-9. Epub 2011 Mar 1. PMID: 21371747.

3. Albert MS, DeKosky ST, Dickson D, Dubois B, Feldman HH, Fox NC, 3 Gamst A, Holtzman DM, Jagust WJ, Petersen RC, Snyder PJ, Carrillo MC, Thies B, Phelps CH. The diagnosis of mild cognitive impairment due to Alzheimer's disease: recommendations from the National Institute on Aging-Alzheimer's Association workgroups on diagnostic guidelines for Alzheimer's disease. Alzheimers Dement. 2011 May;7(3):270-9. doi: 10.1016/j.jalz.2011.03.008. Epub 2011 Apr 21. PMID: 21514249; PMCID: PMC3312027. 4. 4.

4. Nasreddine ZS, Phillips NA, Bedirian V, Charbonneau S, Whitehead V, Collin I, Cummings JL, Chertkow H. The Montreal Cognitive Assessment, MoCA; A Brief Screening Tool for Mild Cognitive Impairment. J Am Geriatr Soc. 2005 Apr;53(4):695-9. Doi: 10.111/j.1532-5415.2005. Epub 2019 Mar 29 PMID: 31493356

5. MMSE Mini-Mental State Examination. PAR website. https://www.parinc.com/ Products/Pkey/237.

6. 221AD302 Phase 3 Study of Aducanumab (BIIB037) in Early Alzheimer's Disease (EMERGE). Clinical trials.gov

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8. Aduhelm. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Accessed January 18, 2022.

ELEVIDYS™ (delandistrogene moxeparvovec-rokl)

FDA Approved Indication(s)

Elevidys is an adeno-associated virus vector-based gene therapy indicated for the treatment of ambulatory pediatric patients aged 4 through 5 years with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene.

Policy/Criteria

I. Initial Approval

The provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that the member has met all approval criteria for one dose per lifetime.

- Diagnosis of DMD with documentation showing the following has been determined:
  - A confirmed mutation in the DMD gene; **and**
  - No deletion in exon 8 or exon 9 in the DMD gene; **and**
  - Evaluation of deletions in the DMD gene at exons 1 to 17 and 59 to 71.

- Patient is 4 to 5 years old (at least 4 years and 0 days and less than 6 years old); **and**

- Prescribed by or in consultation with a pediatric neuromuscular specialist with experience in the diagnoses and treatment of DMD; **and**

- Member will discontinue exon skipping therapy (e.g. Amondys 45®, Exondys 51®, Viltepso®, Vyondys 53™) prior to Elevidys administration, if applicable; **and**

- Provider attests to the following:
  - The patient has not received a previous dose of Elevidys, or is being considered for other gene therapy, or investigational cellular therapy for DMD; **and**
  - Therapy administration will be postponed until resolution of infection if the patient shows signs or symptoms of infection.; **and**
  - Provider agrees to the following post-infusion monitoring:
    - Liver function weekly for the first 3 months
    - Platelet counts weekly for the first two weeks
    - Troponin-I levels weekly for the first month; **and**

- Documentation is submitted for all the following:
  - The patient has been on a stable dose of oral corticosteroid (e.g. prednisone, Emflaza, etc.) and will continue, before and for a minimum of 60 days after Elevidys administration to reduce the risk of the immune response as per the package insert; **and**
  - Documentation that the patient has been assessed for anti-AAVrh74 total binding antibody titers with a lab value demonstrating < 1:400; **and**

- Baseline liver function tests (i.e. AST, ALT, bilirubin) have been obtained in the past 90 days to rule-out pre-existing liver dysfunction; **and**
- Baseline troponin-I levels and platelet counts have been obtained in the past 90 days; **and**
- Patient is ambulatory (e.g. able to walk independently or with some assistance) as evidenced by functional assessment within the last 90 days (e.g. 6-minute walk test, North Star Ambulatory Assessment, 10-meter walk test, Ascend 4 steps, Time to Rise, 100-meter timed test); **and**
- Member does not have evidence of significantly impaired cardiovascular function or hepatic impairment (including acute liver disease, chronic hepatic impairment or elevated GGT) determined by the treating prescriber, which includes clinical rationale.; **and**
- The weight of the patient, the date the weight was obtained, and the number of requested vials is included.**; and**
- The dose does not exceed the package insert at 1.33×10^{14} vector genomes (vg)/kg**.;**

II. Continuation of Therapy:

This cannot be reviewed since the product is currently indicated for one dose per lifetime.

REFERENCES

1. Elevidys Prescribing Information. Cambridge, MA: Sarepta Therapeutics, Inc.; June 2023. Available at: https://www.elevidys.com/PI. Accessed February 23, 2024.

2. ClinicalTrials.gov. A randomized, double-blind, placebo-controlled study of SRP-9001 (delandistrogene moxeparvovec) for Duchenne muscular dystrophy (DMD). Available at: https://www.clinicaltrials.gov/ct2/show/NCT03769116. Accessed February 23, 2024.

3. ClinicalTrials.gov. A gene transfer therapy study to evaluate the safety of and expression from SRP-9001 (delandistrogene moxeparvovec) in participants with Duchenne muscular dystrophy (DMD) (ENDEAVOR). Available at: https://www.clinicaltrials.gov/ct2/show/NCT04626674. Accessed February 23, 2024.

4. Gloss D, Moxley RT, Ashwal S, Oskoui M. Practice guideline update summary: corticosteroid treatment of Duchenne muscular dystrophy. Report of the guideline development subcommittee of the American Academy of Neurology. Neurology. 2016; 86:465-472.

5. Birnkrant DJ, Bushby K, Bann CM, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management. Lancet Neurol. 2018; 17(3):251-267.

HEMGENIX (entranacogene dezaparvovec)

FDA Approved Indication(s)

Hemgenix is an adeno-associated virus vector-based gene therapy indicated for treatment of adults with Hemophilia B (congenital Factor IX deficiency) who currently use Factor IX prophylaxis therapy, have current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes.

Policy/Criteria

I. Initial Approval

The provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that the member has met all approval criteria for one-time dosing.

- Diagnosis of congenital Hemophilia B (factor IX deficiency)**; and**
- Patient is 18 years or older**; and**
- Documentation of endogenous Factor IX levels ≤ 1% (0.01 IU/mL)**; or**
- Documentation of endogenous Factor IX levels ≤ 2% (0.02 IU/mL)**; and**
- Patient has one of the following while on routine prophylaxis factor replacement therapy:
  - Repeated, serious spontaneous bleeding episodes**; or**
  - History of life-threatening or repeated serious bleeding episodes**; and**
- Prescribed and administered by a provider in a Hemophilia Treatment Center or in consultation with a Hemophilia Treatment Center by a physician with experience treating Hemophilia B**; and**
- Provider attests that the patient has not received, or is being considered for other gene therapy, or investigational cellular therapy for hemophilia**; and**
- Provider attests that the dose does not exceed the package insert at 2×10^{13} gc/kg.**; and**
- The patient does not have HIV **or** is HIV positive **and** the provider attests that the patient is virally suppressed (≤200 copies/mL) for 1 year.**; and**
- Documentation is submitted for all the following:
  - The patient has been evaluated for the presence of preexisting neutralizing antibodies to the adenovirus vector (e.g., AAV-5) used to deliver the therapy**; and**
  - Documentation that the patient does not have anti-AAV antibody (e.g., AAV-5) titers exceeding 1:678**; and**

- Provider attests there is no presence or history of Factor IX inhibitors. If a positive lab test occurred, a re-test should be performed in two weeks**; and**
- Patient does not have a history of inhibitors with documentation of a negative inhibitor lab value within the 1 year should be submitted.; (A positive inhibitor value is a Bethesda titer of $\geq$ 0.3 BU for Factor IX[3].)**; and**
- Documentation showing the patient is stable and adherent for the past 150 days on regularly dosed prophylaxis Factor IX therapy**; and**
- Patient is not currently using antiviral therapy for hepatitis B or C**; and**
- Provider attests that liver health assessments including enzyme testing [alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP) and total bilirubin)] and hepatic ultrasound and elastography have been performed to rule out radiological liver abnormalities and that there is not a history of sustained liver enzyme elevations.**; and**
- The weight of the patient, the date the weight was obtained, and the number of requested vials is included.**; and**
- Documentation of lab tests within the past 90 days showing the following:
  - Negative hepatitis B surface antigen**; and**
  - Negative hepatitis C virus (HCV)**; or**
  - HCV antibody is positive AND HCV RNA is negative**; and**
  - AST and ALT are less than 3 times the upper limit of normal

II. Continuation of Therapy:

This cannot be reviewed since the product is currently indicated for a one-time administration.

REFERENCES

1. Hemgenix Prescribing Information. Kankakee, IL: CSL Behring; November 2022. Available at: https://labeling.cslbehring.com/PI/US/Hemgenix/EN/Hemgenix-Prescribing-Information.pdf. Accessed June 23, 2023.

2. ClinicalTrials.gov. HOPE-B: Trial of AMT-061 in severe or moderately severe hemophilia b patients. Available at: https://clinicaltrials.gov/ct2/show/NCT03569891. Accessed November 30, 2022.

3. Srivastava A, Santagostino E, Dougall A, et al. WFH Guidelines for the Management of Hemophilia, 3rd edition. Haemophilia. 2020 Aug;26 Suppl 6:1-158.

KISUNLA (Donanemab-azbt)

FDA Approved Indication(s)

Kisunla is indicated for the treatment of Alzheimer's disease (AD). Treatment with Kisunla should be initiated in patients with mild cognitive impairment (MCI) or mild dementia stage of disease, the population in which treatment was initiated in the clinical trials.

Policy/Criteria

I. Initial Approval

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. Initial approval is for 6 months.

- Prescribed by or in consultation with a dementia specialist (e.g. neurologist, geriatrician, OR Psychiatrist. If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests**; and**

- Provider attestation that the member has a diagnosis of mild cognitive impairment (MCI) due to AD or mild dementia associated with AD disease dementia**; and**

- Patient is ≥ 60 or less ≤ 85 years of age**; and**

- Confirmation of beta-amyloid plaques verified by one of the following within 3-6 months of Kisunla administration/initiation:
  - Positron emission tomography (PET) scan **or**
  - Lumbar puncture for cerebrospinal fluid (CSF) testing**; and**

- Prescriber has assessed and documented baseline disease severity utilizing one of the following scores within the past 3-6 months:
  - Mini-Mental Status Exam (MMSE) score 20-28**; or**
  - Montreal Cognitive Assessment (MoCA) ≥ 15**; or**
  - Clinical Dementia-Global Score 0.5 or 1**; and**

- Documentation within medical record member does not have ANY of the following:
  - Member does NOT have any medical or neurological condition (other than Alzheimer's Disease), including but not limited to Lewy body dementia, frontotemporal dementia, vascular dementia))**; and**
  - History of transient ischemic attacks (TIA), stroke or seizures within the past 12 months**; and**
  - A review of medications is not contributing substantially to cognitive impairment (see Beer's list); **and**
  - Bleeding disorder that is not under adequate control (including a platelet count less than 50,000 or international normalized ratio [INR] greater than 1.5); **or**

- If there is concurrent use of antithrombotic medications (aspirin, other antiplatelets, or anticoagulants), the member has been on a stable dose for at least 4 weeks prior to initiation of the requested medication**; and**

- Member does NOT have any significant cerebrovascular disease as established by brain MRI showing any of the following (within the past year before starting treatment):
  - greater than four microhemorrhages (defined as ≤ 10 mm in diameter**); and**
  - microhemorrhages (defined as >10 mm in diameter)**; and**
  - superficial siderosis**; and**
  - evidence of vasogenic edema**; and**
  - evidence of cerebral contusion, aneurysms or vascular malformations**; and**
  - evidence of multiple lacunar infarcts, severe small vessel or white matter disease**; and**

- Member must have a brain magnetic resonance imaging (MRI) within one year prior to initiating treatment to evaluate for pre-existing Amyloid Related Imaging Abnormalities (ARIA)**; and**

- Member meets one of the following regarding apolipoprotein E ε4 (ApoE ε4) status:
  - Genotype testing for ApoE ε4 status has been performed prior to initiation of treatment to inform member of the risk of developing ARIA**; or**
  - Genotype testing has not been performed and the prescriber has informed the member that it cannot be determined if they are ApoE ε4 homozygous and may be at higher risk for ARIA.**; and**

- Prescriber attests to the following:
  - The dose will not exceed 700 mg for the first, second and third infusions. The dose will not exceed 1400 mg for infusion four and beyond**; and**
  - Follow-up MRI will be obtained and reviewed by the prescriber before the following infusions: 2nd, 3rd, 4th and 7th and then as needed at any time thereafter if the patient experiences symptoms suggestive of ARIA.**;**
  - Member has been evaluated for risk factors for intracerebral hemorrhage, cerebral microangiopathy and/or anticoagulant therapy **AND** the therapeutic risk/benefit has been discussed with the member and/or caregiver**; and**
  - Kisunla will not be combined with other amyloid beta-directed antibodies (e.g., lecanemab-irmb).

II. Continuation of Therapy:

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. Continuation of approval is for 1 year.

- Member has met all initial authorization criteria at the time of initial approval**; and**

- Member has a positive clinical response as evidenced by stabilization or slowing of disease progression as documented by any of the following (**Note**: repeat assessment tool(s) must be the same tool that was submitted upon initial request):
  - MMSE (i.e., decline of 3 points or less per year)**; or**
  - MoCA (i.e., score of greater than or equal to 15)**; or**
  - CDR-Global Score (i.e., score of 0.5 or 1)**; and**

  Note: Continuation requests for members with assessment scores outside of the provided ranges (i.e. mild dementia) or who have progressed greater than the provided rate of decline may be reviewed on a case-by-case basis.

- For members with radiographic evidence of amyloid-related imaging abnormalities-edema (**ARIA-E**):
  Dosing may continue based on clinical judgement, if applicable, for members that meet the following criteria:
  - Member has mild ARIA-E on MRI and is asymptomatic or has mild clinical symptoms**; or**
  - Dosing should be suspended until MRI demonstrates radiographic resolution and symptoms resolve for members that meet any of the following criteria:
    - Member has mild ARIA-E on MRI and has moderate or severe clinical symptoms**; or**
    - Member has moderate ARIA-E on MRI and is asymptomatic or has mild, moderate, or severe clinical symptoms**; or**
    - Member has severe ARIA-E on MRI and is asymptomatic or has mild, moderate, or severe clinical symptoms**; or**

- For members with radiographic evidence of amyloid related imaging abnormalities-hemosiderin deposition (**ARIA-H**):
  - Dosing may continue for members that meet the following criteria:
    - Member has mild ARIA-H on MRI and is asymptomatic**; or**
  - Dosing should be suspended until MRI demonstrates radiographic stabilization and symptoms resolve for members that meet **any of** the following criteria:
    - Member has mild ARIA-H on MRI and is symptomatic**; or**
    - Member has moderate or severe ARIA-H on MRI and is asymptomatic or symptomatic**; and**

- Documentation is submitted evaluating the presence of ARIA on MRI prior to the 2nd, 3rd, 4th and 7th dose.

REFERENCES

1. Centers for Medicare & Medicaid Services. Monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease. Medicare Coverage Database. CAG099469N; 2022. Available at: Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD) | CMS. Accessed October 12, 202

2. Kisunla Prescribing Information. Indianapolis, IN: Eli Lilly and Co.; July 2024. Available at: https://pi.lilly.com/us/kisunla-uspi.pdf?s=pi. Accessed November 7, 2024.

3. Milani SA, Marsiske M, Cottler LB, Chen X, Striley CW. Optimal cutoffs for the Montreal Cognitive Assessment vary by race and ethnicity. Alzheimers Dement (Amst). 2018 Nov 3;10:773-781. doi: 10.1016/j.dadm.2018.09.003. PMID: 30505927; PMCID: PMC6247398.

4. Mintun MA, Lo AC, Duggan Evans C, et al. Donanemab in early Alzheimer's disease. N Engl J Med 2021;384:1691-1704. doi: 10.1056/NEJMoa2100708

5. O'Bryant SE, Waring SC, Cullum CM, et al. Staging dementia using Clinical Dementia Rating Scale Sum of Boxes Scores: a Texas Alzheimer's Research Consortium study. Arch Neurol 2008 August;65(8):1091–1095. doi:10.1001/archneur.65.8.1091.

6. Swanson CJ, Zhang Y, Dhadda S, et al. A randomized, double-blind, phase 2b proof-of concept clinical trial in early Alzheimer's disease with lecanemab, an anti-Aβ protofibril antibody [published correction appears in Alzheimers Res Ther. 2022 May 21;14(1):70]. Alzheimers Res Ther. 2021;13(1):80. Published 2021 Apr 17. doi:10.1186/s13195-021 00813-8

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LEQEMBI (Lecanemab-irmb)

FDA Approved Indication(s)

Lecanemab-irmb (Leqembi™) is a monoclonal antibody targeting amyloid beta that is indicated for the treatment of Alzheimer's disease (AD). Treatment with Leqembi should be initiated in patients with mild cognitive impairment (MCI) or mild dementia stage of disease, the population in which treatment was initiated in clinical trials.

Policy/Criteria

I. Initial Approval

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. Initial approval is for 6 months.

- Prescribed by or in consultation with a dementia specialist (e.g. neurologist, geriatrician, OR Psychiatrist. If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests**; and**

- Provider attestation that the member has a diagnosis of mild cognitive impairment (MCI) due to AD or mild dementia associated with AD disease dementia**; and**

- Patient is ≥ 50 or less ≤ 90 years of age (6)**; and**

- Confirmation of beta-amyloid plaques verified by one of the following:
  - Positron emission tomography (PET) scan **or**
  - Lumbar puncture for cerebrospinal fluid (CSF) testing**; and**

- Prescriber has assessed and documented baseline disease severity utilizing one of the following scores (within the past 6 months):
  - Mini-Mental Status Exam (MMSE) score ≥ 22**; or**
  - Montreal Cognitive Assessment (MoCA) ≥ 15**; or**
  - Clinical Dementia-Global Score 0.5 or 1**; and**

- Prescriber has objectively assessed episodic memory and determined impairment per standard tests [i.e., Free and Cued Selective Reminding Test, the Rey Auditory Verbal Learning Test, the California Verbal Learning Test, or the Logical Memory I and II of the Wechsler Memory Scale Revised (or other versions)] (within the past 6 months)**; and**

- Documentation within medical record member does not have ANY of the following:
  - Member does NOT have any medical or neurological condition (other than Alzheimer's Disease), including but not limited to Lewy body dementia, frontotemporal dementia)**; and**
  - History of transient ischemic attacks (TIA), stroke or seizures within the past 12 months**; and**

- Bleeding disorder that is not under adequate control (including a platelet count less than 50,000 or international normalized ratio [INR] greater than 1.5); **or**
- If there is concurrent use of antithrombotic medications (aspirin, other antiplatelets, or anticoagulants), the member has been on a stable dose for at least 4 weeks prior to initiation of the requested medication.**; and**

- Member does NOT have any significant cerebrovascular disease as established by brain MRI showing any of the following (within the past year prior to starting treatment):
  - greater than four microhemorrhages (defined as ≤ 10 mm in diameter**); and**
  - microhemorrhages (defined as >10 mm in diameter)**; and**
  - superficial siderosis**; and**
  - evidence of vasogenic edema**; and**
  - evidence of cerebral contusion, aneurysms or vascular malformations**; and**
  - evidence of multiple lacunar infarcts, severe small vessel or white matter disease**; and**

- Member must have a brain magnetic resonance imaging (MRI) within one year prior to initiating treatment to evaluate for pre-existing Amyloid Related Imaging Abnormalities (ARIA)**; and**

- Member meets one of the following regarding apolipoprotein E ε4 (ApoE ε4) status:
  - Genotype testing for ApoE ε4 status has been performed prior to initiation of treatment to inform member of the risk of developing ARIA**; or**
  - Genotype testing has not been performed and the prescriber has informed the member that it cannot be determined if they are ApoE ε4 homozygous and may be at higher risk for ARIA.**; and**

- Prescriber attests to the following:
  - Dose will not exceed the following 10 mg/kg at a dosing frequency of once every two weeks.**; and**
  - Follow-up MRI will be obtained and reviewed by the prescriber prior to the following infusions: 5th, 7th and 14th, and then as needed at any time thereafter if the patient experiences symptoms suggestive of ARIA.**; and**
  - Leqembi will not be combined with other amyloid beta-directed antibodies (e.g., aducanumab).

II. Continuation of Therapy:

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. Continuation of approval is for 1 year.

- Member has met all initial authorization criteria at the time of initial approval**; and**

- Member has a positive clinical response as evidenced by stabilization or slowing of disease progression as documented by any of the following (**Note**: repeat assessment tool(s) must be the same tool that was submitted upon initial request):
  - MMSE (i.e., decline of 3 points or less per year)**; or**
  - MoCA (i.e., score of greater than or equal to 15)**; or**
  - CDR-Global Score (i.e., score of 0.5 or 1)**; and**

  Note: Continuation requests for members with assessment scores outside of the provided ranges (i.e. mild dementia) or who have progressed greater than the provided rate of decline may be reviewed on a case-by-case basis.

- For members with radiographic evidence of amyloid-related imaging abnormalities-edema (**ARIA-E**):
  Dosing may continue based on clinical judgement, if applicable, for members that meet the following criteria:
  - Member has mild ARIA-E on MRI and is asymptomatic or has mild clinical symptoms**; or**
  - Dosing should be suspended until MRI demonstrates radiographic resolution and symptoms resolve for members that meet any of the following criteria:
    - Member has mild ARIA-E on MRI and has moderate or severe clinical symptoms**; or**
    - Member has moderate ARIA-E on MRI and is asymptomatic or has mild, moderate, or severe clinical symptoms**; or**
    - Member has severe ARIA-E on MRI and is asymptomatic or has mild, moderate, or severe clinical symptoms**; or**

- For members with radiographic evidence of amyloid related imaging abnormalities-hemosiderin deposition (**ARIA-H**):
  - Dosing may continue for members that meet the following criteria:
    - Member has mild ARIA-H on MRI and is asymptomatic**; or**
  - Dosing should be suspended until MRI demonstrates radiographic stabilization and symptoms resolve for members that meet **any of** the following criteria:
    - Member has mild ARIA-H on MRI and is symptomatic**; or**
    - Member has moderate ARIA-H on MRI and is asymptomatic or symptomatic**; and**

- Documentation is submitted evaluating the presence of ARIA on MRI prior to the 5th, 7th and 14th dose.

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PIASKY (Crovalimab-akkz)

FDA Approved Indication(s)

Crovalimab-akkz (PiaSky) is a monoclonal antibody indicated for the treatment of adult and pediatric patients 13 years and older with paroxysmal nocturnal hemoglobinuria (PNH).

Policy/Criteria

I. Initial Approval

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. Initial approval is for 6 months.

- Prescribed by or in consultation with a hematologist or other appropriate specialist in the treatment of PNH**; and**

- Diagnosis of PNH confirmed by both of the following:
  - The absence or deficiency of glycosylphosphatidylinositol-anchored proteins (GPI-APs) (e.g., at least 5% PNH cells, at least 51% of GPI-AP deficient poly-morphonuclear cells); **and**
  - Flow cytometry is used to demonstrate GPI-APs deficiency; **and**

- Patient is ≥ 13 years of age**; and**

- Member has completed or updated vaccination for meningococcal bacteria (for serogroups A, C, W, Y and B) at least 2 weeks before the first dose of PiaSky; **or**

- Provider submits documentation explaining why the risks of delaying therapy outweigh the risk of developing infection; **and**

- Clinical documentation is submitted to verify the following:
  - Weight of the member in the past 90 days (in kg, and greater than 40 kg); **and**
  - PiaSky will not be prescribed with another FDA-approved therapy for PNH (e.g. Bkemv, Epysqli, Soliris, Ultomiris, Empaveli, Fabhalta, Voydeya); **and**
  - The prescriber attests that they are enrolled in the PiaSky REMS program; **and**
  - Laboratory results or a description of the signs and symptoms attributed to PNH (e.g. LDH > 1.5 ULN, thrombosis, renal dysfunction, pulmonary hypertension, dysphagia, abdominal pain, anemia, dyspnea, extreme fatigue, unexplained/unusual thrombosis, hemolysis/hemoglobinuria, etc.)

II. Continuation of Therapy:

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that the member has met all approval criteria. Continuation of approval is for 1 year.

- Documentation of the member's current body weight (in kg)**; and**
- Member has a positive clinical response as evidenced by, including but not limited to, improvement in any of the following parameters: improved measures of the intravascular hemolysis or extravascular hemolysis (e.g., normalization of LDH, reduced absolute reticulocyte count, reduced bilirubin), reduced need for red blood cell transfusions, increased or stabilization of hemoglobin levels, less fatigue, fewer thrombotic events, etc.; **and**
- Member has shown no signs of unacceptable toxicity or disease progression.; **and**
- Provider attests that PiaSky is not prescribed concurrently with another FDA-approved product for PNH (e.g., Bkemv, Epysqli, Soliris, Ultomiris, Empaveli, Fabhalta, Voydeya).

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KENTUCKY MEDICAID FEE-FOR-SERVICE
PHYSICIAN ADMINISTERED PRIOR AUTHORIZATION CRITERIA

ROCTAVIAN™ (valoctocogene roxaparvovec-rvox)

FDA Approved Indication(s)

Roctavian™ is an adeno-associated virus vector-based gene therapy indicated for the treatment of adults with severe hemophilia A (congenital factor VIII deficiency) with factor VIII activity < 1 IU/dL) without pre-existing antibodies to adeno-associated virus serotype 5 detected by an FDA-approved test. This drug has been discontinued by the manufacturer and will be available until the end of May 2026.

Policy/Criteria

I. Initial Approval

- The provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that the member has met all approval criteria for one dose per lifetime. Diagnosis of congenital hemophilia A (factor VIII (FVIII)deficiency)**; and**

- Patient is 18 years or older**; and**

  - Lab value demonstrating severe hemophilia A in the absence of exogenous factor VIII (defined as pre-treatment FVIII activity<1 IU/dL); **or**

  - The patient meets both of the following:
    - The patient has been adherent with using FVIII product for routine prophylaxis for at 150 days as assessed and documented by the provider; **and**
    - Evidence of any bleeding disorder not related to hemophilia A has been ruled out.

- The patient is not a female of reproductive potential.; **and**

- Prescribed and administered by a physician with experience treating hemophilia A**; and**

  - The patient is not HIV positive; **or**

  - The patient is HIV positive **and** the provider attests that the patient is virally suppressed (≤200 copies/mL) for 1 year.**; and**

- Provider attests to all of the following:
  - The patient does not have any active infections, either acute or uncontrolled chronic; **and**
  - The patient does not have a known hypersensitivity to mannitol; **and**
  - The patient does not have any known significant hepatic fibrosis (stage 3 or 4) or cirrhosis; **and**
  - The patient does not have a history of inhibitors.; **and**

- The patient has not received a prior dose of Roctavian or other gene therapy, or is being considered for other gene therapy, or investigational cellular therapy for hemophilia**; and**
- Alcohol abstinence education has been completed with the member; **and**
- Patient Factor VIII activity will be monitored periodically post-infusion; **and**
  - Patients with factor VIII activity levels > 5 IU/dl will discontinue exogenous factor VIII therapy prophylaxis; **or**
  - If the patient has Factor VIII activity levels that decrease and/or if bleeding is not controlled, then the presence of Factor VIII will be assessed and the need for prophylaxis will be evaluated.; **and**

- Documentation is submitted for all the following:
  - Negative lab test for pre-existing AAV5 neutralizing antibodies as demonstrated by the FDA-approved companion assay; **and**
    - Patient does not have a history of inhibitors with documentation of a negative inhibitor lab value within the 1 year should be submitted; **or**
    - Member has a FVIII inhibitor level assay < 0.6 Bethesda units on 2 consecutive occasions at least one week apart within the last 12 months; (A positive inhibitor value is a Bethesda titer of > 0.6 BU for Factor VIII.)**; and**
  - Patient is not currently using antiviral therapy for hepatitis B or C**; and**
  - Results and interpretation of findings for liver health assessments including enzyme testing [alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP) and total bilirubin)] and hepatic ultrasound and elastography have been performed to rule out radiological liver abnormalities and that there is not a history of sustained liver enzyme elevations.; **and**
  - The weight of the patient, the date the weight was obtained, and the number of requested vials is included.**; and**
  - The dose does not exceed the package insert at 6 x 10^{13} vector genomes/kg.**; and**
  - Documentation of lab tests within the past 90 days showing the following:
    - Negative hepatitis B surface antigen**; and**
    - Negative hepatitis C virus (HCV)**; or**
    - HCV antibody is positive **AND** HCV RNA is negative**; and**

II. Continuation of Therapy:

This cannot be reviewed since the product is currently indicated for a one dose per lifetime administration.

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VYJUVEK (beremagene geperpavec-svdt)

FDA Approved Indication(s)

Vyjuvek is a herpes-simplex virus type 1 (HSV-1) vector-based gene therapy indicated for the treatment of wounds in patients 6 months and older with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene.

Policy/Criteria

I. Initial Approval

The provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that the member has met all approval criteria for 6 months or 26 doses.

- Patient is 6 months of age or older**; and**
- Patient has not received a skin graft within the past 3 months; **and**
- Documentation is submitted that verifies the patient has a genetically confirmed diagnosis of dystrophic epidermolysis bullosa with mutation in the COL7A1 gene;
- Prescribed by, or in consultation with, a dermatologist or other specialist with expertise in the treatment of DEB**; and**
- Patient has at least one recurrent or chronic open wound that meets all of the following criteria:
  - Adequate granulation tissue; **and**
  - Excellent vascularization; **and**
  - No evidence of active wound infection; **and**
  - No evidence or history of squamous cell carcinoma; **and**
- Member is receiving standard-of-care wound therapy**; and**
- Member has not received or is being considered for other gene therapy, or investigational cellular therapy.

II. Continuation of Therapy:

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. Continuation of approval is for 1 year.

- Patient has previously been treated with Vyjuvek and clinical documentation provided demonstrates a positive clinical response to Vyjuvek therapy (e.g., decrease in wound size, increase in granulation tissue, complete wound closure); **and**

- Clinical documentation is provided to show that the patient had a positive clinical response to Vyjuvek therapy as defined by decrease in wound size, increase in tissue granulation, wound closure, etc.

- Prescribed by, or in consultation with, a dermatologist with expertise in the treatment of DEB**; and**

- Member is receiving standard-of-care wound therapy**; and**

- Member is not on chemotherapy or immunotherapy**; and**

- Member has not received or is being considered for other gene therapy, or investigational cellular therapy.

REFERENCES

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