Mass General Brigham
Health Plan

Alzheimer's Agents
Leqembi ((lecanemab-irmb)
Effective 06/01/2025

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693 **Non-Specialty Medications** All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Notes	Leqembi is also available on the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria. Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.		

Overview
Leqembi (lecanemab-irmb) is indicated for the treatment of Alzheimer's disease. Treatment with Leqembi should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. It initially received accelerated approval similar to Aduhelm, but subsequently received a traditional approval after a clinical benefit was established. Of note, while Leqembi appears to be a safer alternative than Aduhelm, there a black box warning for amyloid-related imaging abnormalities (ARIA), particularly those patients who are apolipoprotein E (ApoE) ε4 homozygotes.

Coverage Guideline
Authorization may be granted for new members to the plan who are currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs, when continuation of therapy criteria is met.
OR
Authorization may be granted for members when all the following criteria are met:

1. Diagnosis of ONE of the following:
    a. Mild cognitive impairment (MCI)
    b. Mild dementia associated with Alzheimer's Disease (AD)
2. Prescriber is a specialist in the treatment of dementia or Alzheimer's disease (e.g., neurologist, geriatric psychiatrist, geriatrician who specializes in treating dementia)
3. Test results indicating clinically significant AD neuropathology based on ONE of the following:
    a. Amyloid PET
    b. Cerebral Spinal Fluid (CSF) biomarkers
4. Member has had a brain magnetic resonance imaging (MRI) within the last 12 months
5. Appropriate dosing

6. Baseline cognitive function test (within the last three months) based on ONE of the following objective assessments:
    a. Mini Mental State Exam (MMSE) score ≥ 22
    b. Montreal Cognitive Assessment (MoCA) score ≥ 15
    c. Saint Louis University Mental Status Examination (SLUMS) score ≥ 16.1

Continuation of Therapy

First reauthorization:

1. Appropriate dosing
2. Attestation that all MRI monitoring has been completed in accordance with the FDA approved label
3. Current cognitive function test (within the past three months) based on ONE of the following objective assessments:
    a. Mini Mental State Exam (MMSE)
    b. Montreal Cognitive Assessment (MoCA)
    c. Saint Louis University Mental Status Examination (SLUMS)

Subsequent reauthorization (after completion of 18 months of treatment):

1. Attestation that all MRI monitoring has been completed in accordance with the FDA approved label
2. Current cognitive function test (within the past three months) based on ONE of the following objective assessments:
    a. Mini Mental State Exam (MMSE)
    b. Montreal Cognitive Assessment (MoCA)
    c. Saint Louis University Mental Status Examination (SLUMS)
3. ONE of the following:
    a. Dosing frequency reduced to every four weeks
    b. Clinical rationale for continuing biweekly dosing

Limitations

1. Initial approvals will be granted for 6 months.
2. Reauthorizations will be granted for 12 months.

References

1. American Psychiatric Association: diagnostic and statistical manual of mental disorders, 4th ed, text revision. [monograph on the internet]. Washington: American Psychiatric Association, 2000 [cited 2015 May]. Available from: http://online.statref.com/Document/Document.aspx?docAddress=JGvR966ghWBjdaA-RZrSWg%3d%3d&Scroll=2&Index=9&SessionId=148566DBPFWRIJKR.
2. Alzheimer's Association. Alzheimer's disease Facts and Figures, 2007 [monograph on the internet]. Washington (DC): Alzheimer's Association; 2007 [cited 2015 May]. Available from: http://www.alz.org/national/documents/Report_2007FactsAndFigures.pdf.
3. Hebert LE, Scherr PA, Bienias JL, Bennett DA, Evans DA. Alzheimer disease in the US population: prevalence estimates using the 2000 census. Arch Neurol. 2003 Aug;60(8):1119-22.
4. Slattum PW, Swerdlow RH, Hill AM. Alzheimer's Disease. In: DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey LM, editors. Pharmacotherapy: A Pathophysiologic Approach. 7th Edition. New York: McGraw-Hill; 2008; 1051-65.
5. Larson EB, Shadlen MF, Wang L, McCormick WC, Bowen JD, Teri L, Kukull WA. Survival after initial diagnosis of Alzheimer disease. Ann Intern Med. 2004 Apr 6;140(7):501-9.

6. Wolk DA, Dickerson BC. Clinical features and diagnosis of Alzheimer disease. In: Eichler AF (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2017 [cited 2017 May 3]. Available from: http://www.utdol.com/utd/index.do.
7. Drugs@FDA [database on the Internet]. Rockville (MD): Food and Drug Administration (US), Center for Drug Evaluation and Research; 2013 [cited 2015 May]. Available from: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm.
8. Actavis and Adamas Announce FDA Approval of Namzaric™, a Fixed-Dose Combination of Memantine Extended-Release and Donepezil Hydrochloride [press release on the Internet]. Dublin and Emeryville (CA): Food and Drug Administration (US); 2014 Dec 24 [cited 2015 August]. Available from: http://www.actavis.com/news/news/thomson-reuters/actavis-and-adamas-announce-fda-approval-of-namzar
9. Press D, Alexander M. Cholinesterase inhibitors in the treatment of dementia. In Eichler AF (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2017 [cited 2017 May 3]. Available from: https://www.uptodate.com/contents/search.
10. Hosenbocus S, Chahal R. Memantine: a review of possible uses in child and adolescent psychiatry. J Can Acad Child Adolesc Psychiatry. 2013 May;22(2):166-71.
11. Owley T, Salt J, Guter S, Grieve A, Walton L, Ayuyao N, Cook E. A prospective, open-label trial of memantine in the treatment of cognitive, behavioral, and memory dysfunction in pervasive developmental disorders. Journal of Child and Adolescent Psychopharmacology. 2006;16(5):517–524.
12. Erikson C, Posey D, Stigler K, Mullet J, Katschke A, McDougle C. A retrospective study of memantine in children and adolescents with pervasive developmental disorders. Psychopharmacology. 2007;191(1):141–147.
13. Chez M, Burton Q, Dowling T, Change M, Khanna P, Kramer C. Memantine as adjunctive therapy in children diagnosed with autistic spectrum disorders: An observation of initial clinical response and maintenance tolerability. Journal of Child Neurology. 2007;22(5):574–579.
14. Ghaleiha A, Asadabadi M, Mohammadi M, Shahei M, Tabrizi M, Hajiaghaee R, Akhondzadeh S. Memantine as adjunctive treatment to risperidone in children with autistic disorder: A randomized, double-blind, placebo-controlled trial. International Journal of Neuropsychopharmacology, First view. 2012;(1):1–7.
15. Aman MG, Findling RL, Hardan AY, Hendren RL, Melmed RD, Kehinde-Nelson O, et al. Safety and Efficacy of Memantine in Children with Autism: Randomized, Placebo-Controlled Study and Open-Label Extension. J Child Adolesc Psychopharmacol. 2016 Mar 15. doi: 10.1089/cap.2015.0146. [Epub ahead of print].
16. Hardan AY, Handen BL. A retrospective open trial of adjunctive donepezil in children and adolescents with autistic disorder. J Child Adolesc Psychopharmacol. 2002 Fall;12(3):237-41.
17. Handen BL, Johnson CR, McAuliffe-Bellin S, Murray PJ, Hardan AY. Safety and efficacy of donepezil in children and adolescents with autism: neuropsychological measures. J Child Adolesc Psychopharmacol. 2011 Feb;21(1):43-50. doi: 10.1089/cap.2010.0024.
18. Buckley AW, Sassower K, Rodriguez AJ, Jennison K, Wingert K, Buckley J, et al. An open label trial of donepezil for enhancement of rapid eye movement sleep in young children with autism spectrum disorders. J Child Adolesc Psychopharmacol. 2011 Aug;21(4):353-7. doi: 10.1089/cap.2010.0121.
19. Ghaleiha A, Ghyasvand M, Mohammadi MR, Farokhnia M, Yadegari N, Tabrizi M, et al. Galantamine efficacy and tolerability as an augmentative therapy in autistic children: A randomized, double-blind, placebo-controlled trial. J Psychopharmacol. 2014 Jul;28(7):677-85. doi: 10.1177/0269881113508830. Epub 2013 Oct 15.
20. Nicolson R, Craven-Thuss B, Smith J. A prospective, open-label trial of galantamine in autistic disorder. J Child Adolesc Psychopharmacol. 2006 Oct;16(5):621-9.
21. Chez MG, Aimonovitch M, Buchanan T, Mrazek S, Tremb RJ. Treating autistic spectrum disorders in children: utility of the cholinesterase inhibitor rivastigmine tartrate. J Child Neurol. 2004 Mar;19(3):165-9.

22. Findling R, McNamara N, Stansbrey R, Maxhimer R, Periciou A, Mann A, Graham S. A pilot evaluation of the safety, tolerability, pharmacokinetics, and effectiveness of memantine in pediatric patients with attention-deficit/hyperactivity disorder combined type. Journal of Child Adolescent Psychopharmacology. 2007;17(1):19–33.
23. Wilens TE, Waxmonsky J, Scott M, Swezey A, Kwon A, Spencer TJ, et al. An open trial of adjunctive donepezil in attention-deficit/hyperactivity disorder. J Child Adolesc Psychopharmacol. 2005 Dec;15(6):947-55.
24. Cubo E, Fernández Jaén A, Moreno C, Anaya B, González M, Kompoliti K. Donepezil use in children and adolescents with tics and attention-deficit/hyperactivity disorder: an 18-week, single-center, dose-escalating, prospective, open-label study. Clin Ther. 2008 Jan;30(1):182-9. doi: 10.1016/j.clinthera.2008.01.010.
25. Hezel D, Beattie K, Stewart S. Memantine as an augmenting agent for severe pediatric OCD. American Journal of Psychiatry. 2009;166(2):237.
26. Niederhofer H. Glutamate antagonists seem to be slightly effective in psychopharmacologic treatment of autism. Journal of Clinical Psychopharmacology. 2007;27(3):317.
27. Joshi G, Wozniak J, Faraone SV, Fried R, Chan J, Furtak S, et al. A Prospective Open-Label Trial of Memantine Hydrochloride for the Treatment of Social Deficits in Intellectually Capable Adults With Autism Spectrum Disorder. J Clin Psychopharmacol. 2016 Jun;36(3):262-71. doi: 10.1097/JCP.0000000000000499.
28. Surman CB, Hammerness PG, Petty C, Spencer T, Doyle R, Napolean S, et al. A pilot open label prospective study of memantine monotherapy in adults with ADHD. World J Biol Psychiatry. 2013 May;14(4):291-8. doi: 10.3109/15622975.2011.623716. Epub 2012 Mar 22.
29. Ghaleiha A, Entezari N, Modabbernia A, Najand B, Askari N, Tabrizi M, Akhondzadeh S. Memantine add-on in moderate to severe obsessive-compulsive disorder: Randomized double-blind placebo-controlled study. Journal of Psychiatric Research. 2013;47(2):175–180.
30. Aboujaoude E, Barry J, Gamel M. Memantine augmentation in treatment-resistant obsessive compulsive disorder: An open label trial. Journal of Clinical Psychopharmacology. 2009;29(1):51–55.
31. Stewart S, Jenike E, Hezel D, Stack D, Dodman N, Shuster L, Jenike M. A single blinded case control study of memantine in severe obsessive compulsive disorder. Journal of Clinical Psychopharmacology. 2010;30(1):34–39.
32. Lieberman J, Papadakis K, Csernansky J, Litman R, Volavka J, Jia X, Gage A. A randomized, placebo-controlled study of memantine as adjunctive treatment in patients with schizophrenia. Neuropsychopharmacology. 2009;34(1):1322–1329.
33. Krivoy A, Weizman A, Laor L, Hellinger N, Zemishlany Z, Fischel T. Addition of memantine to antipsychotic treatment in schizophrenia inpatients with residual symptoms: A preliminary study. European Neuropsychopharmacology. 2008;18(2):117–121.
34. de Lucena D, Fernandes B, Berk M, Dodd S, Medeiros D, Pedrini M, Gama C. Improvement of negative and positive symptoms in treatment-refractory schizophrenia: A double-blind, randomized, placebo-controlled trial with memantine as addon therapy to clozapine. Journal of Clinical Psychiatry. 2009;70(10):1416–1423.
35. Carroll B, Thomas C, Jayanti K. Amantadine and memantine in catatonic schizophrenia. Annals of Clinical Psychiatry. 2006;18(2):133–134.
36. Rezaei F, Mohammad-Karimi M, Seddighi S, Modabbernia A, Ashrafi M, Salehi B, et al. Memantine add-on to risperidone for treatment of negative symptoms in patients with stable schizophrenia: randomized, double-blind, placebo-controlled study. J Clin Psychopharmacol. 2013 Jun;33(3):336-42. doi: 10.1097/JCP.0b013e31828b50a7.
37. Zarate C, Singh J, Carlson P, Brutsche N, Ameli R, Luckenbaugh D, Manji H. A randomized trial of an N-methyl-D-asparate antagonist in treatment-resistant major depression. Archives of General Psychiatry. 2006;63(8):856–864.
38. Ferguson J, Shingleton R. An open-label, flexible dose study of memantine in major depressive disorder. Clinical Neuropharmacology. 2007;30(3):136–144.

39. Muhonen L, Lonnqvist J, Juva K, Alho H. Double-blind, randomized comparison of memantine and escitalopram for the treatment of major depressive disorder comorbid with alcohol dependence. Journal of Clinical Psychiatry. 2008;69(3):392–399.
40. Kollmar R, Markovic K, Thurauf N, Schmitt H, Kornhuber J. Ketamine followed by memantine for the treatment of major depression. Australian & New Zealand Journal of Psychiatry. 2008;42(2):170.
41. Koukopoulos A, Reginaldi D, Serra G, Koukopoulos AE, Sani G, Serra G. Antimanic and mood-stabilizing effect of memantine as an augmenting agent in treatment-resistant bipolar disorder. Bipolar Disorders. 2010;12(3):348–349.
42. Koukopulos A, Serra G, Koukopoulos AE, Serra G. The sustained mood-stabilizing effect of memantine in the management of treatment resistant bipolar disorders: Findings from a 12-month naturalistic trial. Journal of Affective Disorders. 2012;136(1–2):163–166.
43. Keck P, Hsu H, Papadakis K, Russo J. Memantine efficacy and safety in patients with acute mania associated with bipolar 1 disorder: A pilot evaluation. Clinical Neuropharmacology. 2009;32(4):199–204.
44. Anand A, Gunn A, Barkay G, Karne H, Nurnberger J, Matthew S, Ghosh S. Early antidepressant effect of memantine during augmentation of lamotrigine inadequate response in bipolar depression: A double-blind, randomized, placebo-contolled trial. Bipolar Disorders. 2012;14(1):64–70.
45. Kishi T, Matsunaga S, Iwata N. A Meta-Analysis of Memantine for Depression. J Alzheimers Dis. 2017;57(1):113-121. doi: 10.3233/JAD-161251.
46. Feusner J, Kerwin L, Saxena S, Bystritsky A. Differential efficacy of memantine for obsessive-compulsive disorder vs generalized anxiety disorder: An open-label trial. Psychopharmacology Bulletin. 2009;42(1):81–93.
47. Schwartz T, Siddiqui U, Raza S. Memantine as an augmentation therapy for anxiety disorders. Case Reports in Psychiatry. 2012;2012(749796):1–3.
48. Micromedex® Healthcare Series [database on the Internet]. Greenwood Village (CO): Thomson Reuters (Healthcare) Inc.; Updated periodically [cited 2015 May]. Available from: http://www.thomsonhc.com/.
49. Drug Facts and Comparisons 4.0 [database on the Internet]. St. Louis: Wolters Kluwer Health, Inc.; 2011 [cited 2015 May]. Available from: http://online.factsandcomparisons.com.
50. Prasher VP. Review of donepezil, rivastigmine, galantamine and memantine for the treatment of dementia in Alzheimer's disease in adults with Down syndrome: implications for the intellectual disability population. Int J Geriatr Psychiatry. 2004 Jun;19(6):509-15.
51. Warden DL, Gordon B, McAllister TW, Silver JM, Barth JT, Bruns J, et al. Guidelines for the pharmacologic treatment of neurobehavioral sequelae of traumatic brain injury. J Neurotrauma. 2006 Oct;23(10):1468-501.
52. Leqembi [package insert]. Nutley (NJ): Eisai, Inc.; 2025 Jan.

Review History

03/16/2022 – Reviewed and Created for March P&T; Match MH criteria Effective 05/01/2022.
01/11/2023 - Reviewed and updated for Jan P&T. Matched MH UPPL criteria. Adlarity was added to pharmacy benefit with PA and QL. Updated approval durations. Effective 3/1/23.
09/13/2023 – Reviewed and updated for P&T. Added Leqembi to criteria. Aduhelm initial criteria: Clarified provider specialty, SLUMS added as another assessment options, changed timeline of MRI scan from 3 to 12 months, and preferred trial of Leqembi. Aduhelm reauth criteria further simplified to require current objective assessments and attestation that all MRI monitoring has been completed. Effective 10/2/23
05/15/25 – Reviewed and updated for P&T. Updated formatting and references. Removed Aduhelm due to removal from the market. Adlarity is removed as it is available on the pharmacy benefit and criteria is available on MHDL. Leqembi remains due to dual benefit. Criteria was updated to remove requirement of medical records and info on PA is acceptable. Reauthorization criteria has been split based on first and subsequent requests. Effective 6/1/25