EMSAM (selegiline) transdermal system
Effective 08/01/2020

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	**Specialty Medications** All Plans | Phone: 866-814-5506 | Fax: 866-249-6155		
	Non-Specialty Medications MassHealth | Phone: 877-433-7643 | Fax: 866-255-7569		
	Commercial | Phone: 800-294-5979 | Fax: 888-836-0730		
	Exchange | Phone: 855-582-2022 | Fax: 855-245-2134		
	Medical Specialty Medications (NLX) All Plans | Phone: 844-345-2803 | Fax: 844-851-0882		
Exceptions	N/A		

Overview
Emsam (selegiline transdermal system) is a monoamine oxidase inhibitor (MAOI) indicated for the treatment of adults with major depressive disorder (MDD)

Coverage Guidelines
Authorization may be granted for members new to the plan who are currently receiving treatment with Emsam, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Approval of EMSAM will be granted if the member meets the ALL the following criteria and documentation has been provided:

1. Member is at least 18 years of age **AND**
2. Member is diagnosed with major depressive disorder (MDD) **AND**
3. Member is unable to tolerate oral medications, including liquid or crushed formulations
   OR
3. Member has had a documented side effect, allergy or treatment failure with at least one SSRI and one other non-SSRI antidepressant
   OR
3. Member has a contradiction to all SSRI and non-SSRI antidepressants

Limitations
1. Approvals will be granted for 36 months
2. The following quantity limits apply:

Emsam	30 patches per month

Pharmacist's Note: EMSAM®, like other antidepressants, contains a Black Box Warning:

Suicidality and Antidepressant Drugs

Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of EMSAM or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised for the need for close observation and communication with the prescriber. EMSAM is not approved for use in pediatric patients. Furthermore, EMSAM at any dose should not be used in children under the age of 12, even when administered with dietary modifications.

References

1. Emsam (selegiline transdermal system) [prescribing information]. Morgantown, WV: Mylan Specialty LP; May 2020
2. American Psychiatric Association (APA). Practice guideline for the treatment of patients with major depressive disorder. 3rd ed. Arlington (VA): American Psychiatric Association (APA); 2010 Oct. Available at: http://psychiatryonline.org/guidelines.aspx
3. Delbello MP, Hochadel TJ, Portland KB, et al. A double-blind, placebo-controlled study of selegiline transdermal system in depressed adolescents. J Child Adolesc Psychopharmacol. 2014 Aug; 24(6):311-7.
4. Jakubovski E, Varigonda AL, Freemantle N, et al. Systematic Review and Meta-Analysis: Dose-Response Relationship of Selective Serotonin Reuptake Inhibitors in Major Depressive Disorder. Am J Psychiatry 2016; 173:174

Review History

12/04/2006 - Implementation
11/27/2006 – Reviewed
11/26/2007 – Reviewed
01/02/2008 - Implementation
11/24/2008 - Reviewed
11/23/2009 – Reviewed
11/22/2010 – Reviewed
11/28/2011 – Reviewed
11/26/2012 – Reviewed
11/25/2013 – Reviewed
11/27/2017 – Reviewed
04/17/2019 – Reviewed
05/20/2020 – Reviewed and Updated May P&T Mtg; added started and stabilized statement; added QL to 'Limitations'. Effective 8/1/20.
07/21/2021-Reviewed July P&T; no clinical changes
11/16/2022 – Reviewed for Nov P&T. Separated out MH vs Comm/Exch. No clinical changes

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