

Initial Prior Authorization

Emsam

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Emsam	selegiline

Indications

FDA-approved Indications

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

Coverage Criteria

Major Depressive Disorder (MDD)

Authorization may be granted when the requested drug is being prescribed for the treatment of an adult patient with major depressive disorder (MDD) when ONE of the following criteria are met:

- The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to ANY of the following: a serotonin and norepinephrine reuptake inhibitor (SNRI), a selective serotonin reuptake inhibitor (SSRI), mirtazapine, bupropion.
- The patient is unable to swallow oral formulations.

Duration of Approval (DOA)

- 867-A: DOA: 36 months

References

1. Emsam [package insert]. Morgantown, WV: Somerset Pharmaceuticals, Inc.; May 2020.
2. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed September 09, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 09/09/2024).
4. Gelenberg AJ, Freeman MP, Markowitz JC, et al. American Psychiatric Association (APA) Practice Guideline for the Treatment of Patients with Major Depressive Disorder, Third Edition. October 2010. Available at: https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf. Accessed September 05, 2024.

Document History

Written by: UM Development (SE)

Date written: 12/2009

Revised: (SE/CT) 09/2010 (CAS adapted); (CT) 08/2011, 06/2012; (PL) 10/2012 (extended duration); (TM) 05/2013; (CF) 05/2014, 05/2015; (CT) 05/2016; (RP) 05/2017; (KC) 05/2018; (CF) 03/2019 (removed BBW question); (DFW) 03/2020 (removed trazodone, tetracyclic and TCAs from try/fail question); (CJH) 02/2021 (no clinical changes); (DS) 02/2022 (no clinical changes); (ASA) 02/2023 (no clinical changes); (KEJ) 02/2024 (no clinical changes); (ASA) 09/2024 (no clinical changes)

Reviewed: Medical Affairs (KP) 12/2009, 10/2010, 08/2011, 06/2012, 10/2012; (LB) 05/2013; (LMS) 05/2014; (DNC) 05/2015; (ME) 05/2016; (LMS) 05/2017; (DC) 05/2018; (CHART) 08/22/2019, 03/26/2020, 02/25/2021, 02/24/2022, 03/02/2023, 02/29/2024, 09/26/2024

External Review: 02/2010, 12/2010, 10/2011, 10/2012, 08/2013, 06/2014, 08/2014, 08/2015, 08/2016, 08/2017, 08/2018, 08/2019, 08/2020, 06/2021, 06/2022, 06/2023, 06/2024, 12/2024

CRITERIA FOR APPROVAL

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| 1 | Is the requested drug being prescribed for the treatment of an adult patient with major depressive disorder (MDD)?
[If Yes, then go to 2. If No, then no further questions.] | Yes | No |
|---|---|-----|----|

2	Has the patient experienced an inadequate treatment response, intolerance, or does the patient have a contraindication to ANY of the following: A) a serotonin and norepinephrine reuptake inhibitor (SNRI), B) a selective serotonin reuptake inhibitor (SSRI), C) mirtazapine, D) bupropion? [If Yes, then no further questions. If No, then go to 3.]	Yes	No
3	Is the patient unable to swallow oral formulations? [No further questions]	Yes	No

Mapping Instructions			
	Yes	No	DENIAL REASONS
1.	Go to 2	Deny	<p>Your plan only covers this drug when it is used for certain health conditions. Covered use is major depressive disorder (MDD) in adults. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Diagnosis]</p>
2.	Approve, 36 Months	Go to 3	
3.	Approve, 36 Months	Deny	<p>Your plan only covers this drug if you have tried other drugs and they did not work well for you. We have denied your request because: A) You have not tried at least one of the following drugs: i) A serotonin and norepinephrine reuptake inhibitor (SNRI), ii) A selective serotonin reuptake inhibitor (SSRI), iii) Mirtazapine, iv) Bupropion, and B) You do not have a medical reason not to take them. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p>

Reference number(s)
867-A

			[Short Description: Step therapy]
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