



# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Emsam Clinical Edit
<b>First Implementation Date:</b>	May 16, 2007
<b>Revised Date:</b>	January 28, 2021
<b>Prepared for:</b>	MO HealthNet
<b>Prepared by:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input checked="" type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** Ensure appropriate utilization and control of Emsam® (selegiline transdermal)

**Why Issue Selected:** Emsam® is a transdermally administered version of selegiline, a monoamine oxidase inhibitor (MAOI). Emsam is indicated for the treatment of major depressive disorder. MAOIs are recognized as having broad efficacy in treating depressive disorders; however, despite their effectiveness, MAOI use is generally reserved for patients who do not respond to other treatments, primarily due to safety concerns, tolerability issues, and the requirement that patients follow a modified diet while taking these agents. MAOIs are associated with the risk of hypertensive crisis related to the ingestion and metabolism of tyramine-containing foods. At lower doses (6mg/24hr patch), Emsam is selective for MAO B and avoids first-pass hepatic metabolism; this allows for no dietary restrictions at the lower dose. However, the higher doses of Emsam (9mg/24hr and 12mg/24hr) are non-selective and inhibit both MAO A and MAO B, thus requiring the tyramine modified diet to reduce the risk of hypertensive crisis; these higher doses are typically required for antidepressant activity. Emsam offers a treatment option for patients not achieving satisfactory response with first-line agents, including SSRIs and SNRIs.

### Program-Specific Information:

Date Range FFS 7-1-2019 to 6-30-2020				
Drug	Claims	Spend	Cost per patch	Cost per month
EMSAM 6MG/24HR PATCH	14	\$24,472.72	\$58.56 WAC	\$1,756.80 WAC
EMSAM 9MG/24HR PATCH	16	\$27,695.40		
EMSAM 12MG/24HR PATCH	0	-		

**Type of Criteria:**  Increased risk of ADE  Preferred Drug List  
 Appropriate Indications  Clinical Edit

**Data Sources:**  Only Administrative Databases  Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: Emsam® (selegiline transdermal)
- Age range: All appropriate MO HealthNet participants aged 18 years and older

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## Approval Criteria

- Participant is aged 18 years or older **AND**
- Documented trial of a SSRI, SNRI, bupropion, or mirtazapine **OR**
- Documented compliance to previous Emsam therapy (defined as 90 days in the past 120 days)

## Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Daily dose exceeds 12mg per day

## Required Documentation

Laboratory Results:   
MedWatch Form:

Progress Notes:   
Other:

## Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)  
Rule Type: CE

## Default Approval Period

1 year

## References

- EMSAM® (selegiline transdermal system) [package insert]. Morgantown, WV: Mylan Specialty L.P.; May 2020.
- Facts & Comparisons. Selegiline Transdermal. Accessed August 3, 2020.
- IPD Analytics. Behavioral Health: Depression. Accessed August 3, 2020.
- American Psychiatric Association. Practice Guideline for the Treatment of Patients with Major Depressive Disorder - Third Edition. <https://psychiatryonline.org/guidelines>. Publication Date: 2010