# SmartPA Criteria Proposal

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|---|---|
| **Drug/Drug Class:** | Emsam Clinical Edit |
| **First Implementation Date:** | May 16, 2007 |
| **Proposed Date:** | September 16, 2021 |
| **Prepared for:** | MO HealthNet |
| **Prepared by:** | MO HealthNet/Conduent |
| **Criteria Status:** | ☒Existing Criteria<br>☐Revision of Existing Criteria<br>☐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. Due to the high cost, possible adverse events, and specific approved indication, MO HealthNet will impose clinical criteria to ensure appropriate utilization of Emsam.

**Program-Specific Information:**

| Date Range FFS 7-1-2019 to 6-30-2020 | | | |
|---|---|---|---|
| **Drug** | **Claims** | **Spend** | **Avg Spend per Claim** |
| EMSAM 6 MG/24 HR PATCH | 17 | $30,107.77 | $1,771.04 |
| EMSAM 9 MG/24 HR PATCH | 36 | $65,159.08 | $1,809.97 |
| EMSAM 12 MG/24 HR PATCH | 0 | - | - |

**Type of Criteria:**
☐ **Increased risk of ADE**
☐ **Appropriate Indications**
☐ **Preferred Drug List**
☒ **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

## 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 12 mg per day

## Required Documentation

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|---|---|---|---|
| Laboratory Results: | | Progress Notes: | |
| MedWatch Form: | | Other: | X |

## 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 4, 2021.
- IPD Analytics. Behavioral Health: Depression. Accessed August 4, 2021.
- American Psychiatric Association. Practice Guideline for the Treatment of Patients with Major Depressive Disorder - Third Edition. https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf. October 2010.