**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.

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Date Range FFS 7-1-2019 to 6-30-2020</th>
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<tbody>
<tr>
<td></td>
<td>Drug</td>
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<tr>
<td>EMSAM 6 MG/24 HR PATCH</td>
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<tr>
<td>EMSAM 9 MG/24 HR PATCH</td>
<td>36</td>
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<tr>
<td>EMSAM 12 MG/24 HR PATCH</td>
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</tbody>
</table>

**Type of Criteria:**
- [ ] Increased risk of ADE
- [ ] Preferred Drug List
- [X] Appropriate Indications
- [X] Clinical Edit

**Data Sources:**
- [ ] Only Administrative Databases
- [X] 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**

<table>
<thead>
<tr>
<th>Laboratory Results:</th>
<th>Progress Notes:</th>
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<tr>
<th>MedWatch Form:</th>
<th>Other:</th>
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**Disposition of Edit**

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

**Default Approval Period**

1 year

**References**