Executive Summary

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

Why was this 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:

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<th>Drug</th>
<th>Date Range FFS 1-1-2019 to 6-30-2019</th>
<th>Claims</th>
<th>Spend</th>
<th>Cost per Unit</th>
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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

Approval Criteria

- Aged 18 years or older AND
- Documented trial of a SSRI, SNRI, bupropion, mirtazapine, nefazodone, or trazodone for 30 days in the past 2 years OR
- Documented compliance to previous Emsam therapy (defined as 90 days in the past 120 days)

Denial Criteria

- Therapy will be denied if no approval criteria are met
- Daily dose exceeds 12mg per day

Required Documentation

Laboratory results:  
MedWatch form:  
Progress notes:  
Other:

Disposition of Edit

Denial: Exception code “682” (Clinical Edit)

References