SmartPA Criteria Proposal

Drug/Drug Class:	Emsam Clinical Edit
First Implementation Date:	May 16, 2007
Revised Date:	October 20, 2022
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐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 4-1-2021 to 3-31-2021			
Drug	**Claims**	**Spend**	**Avg Spend per Claim**
EMSAM 6 MG/24 HR PATCH	10	$15,022.06	$1,502.21
EMSAM 9 MG/24 HR PATCH	29	$54,002.12	$1,862.14
EMSAM 12 MG/24 HR PATCH	1	$1,857.32	$1,857.32

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

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 May 5, 2022.
- American Psychiatric Association. Practice Guideline for the Treatment of Patients with Major Depressive Disorder - Third Edition. PG_Depression3e.book(PG_Depression_3e00Pre.fm) (psychiatryonline.org). October 2010.