SmartPA Criteria Proposal

Drug/Drug Class:	Emsam Clinical Edit
First Implementation Date:	May 16, 2007
Proposed Date:	September 17, 2020
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.

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**
☐ **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 12mg 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 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