Heritage Information Systems, Inc.

SmartPA

Clinical Edit Criteria Proposal

Drug/Drug Class: Emsam® Clinical Edit
Date: May 16, 2007
Prepared for:
Prepared by: Missouri Medicaid

☒ **New Criteria** ☐ **Revision of Existing Criteria**

Executive Summary

Purpose:

Ensure appropriate utilization and control of Emsam® (selegiline transdermal system).

Why was this Issue Selected:

Emsam, a branded drug product containing selegiline, is a monoamine oxidase inhibitor (MAOI), indicated for the treatment of major depressive disorder (MDD). Depression is a widespread, debilitating psychiatric illness with far-reaching clinical and humanistic consequences. According to the World Health Organization, depression is a leading cause of disability worldwide. MAOIs are recognized as having broad efficacy in treating depressive disorders. American Psychiatric Association guidelines suggest MAOIs for patients with atypical depression and for MDD patients with treatment resistant depression. Despite their effectiveness, oral MAOI use has declined in clinical practice, primarily due to safety concerns, tolerability issues, and the requirement that patients follow a modified diet while taking these agents. Oral MAOIs are associated with the risk of hypertensive crisis related to the ingestion and metabolism of tyramine-containing foods. The Emsam 6mg/24Hr patch avoids first-pass hepatic metabolism, therefore there is no requirement of a tyramine modified diet. The higher doses of Emsam 9mg/24Hr and 12mg/24Hr do require the tyramine modified diet to reduce the risk of hypertensive crisis. Emsam offers a treatment option for patients not achieving satisfactory response with first-line agents, including SSRIs and SNRIs.

Program-specific information:

Drug	Cost/Month (AWP)
• *Emsam 6mg/24Hr Patch*	*$481.88*
• *Emsam 9mg/24Hr Patch*	*$481.88*
• *Emsam 12mg/24Hr Patch*	*$481.88*

Setting & Population:	Patients 18 years of age and older	
Type of Criteria:	☐ **Increased risk of ADE**	☐ **Non-Preferred Agent**
	☒ **Appropriate Indications**	☐
Data Sources:	☐ **Only administrative databases**	☒ **Databases + Prescriber-supplied**

Setting & Population

- Drug for review Emsam® (selegiline transdermal system)
- Age range: Patients 18 years of age and older
- Gender: Male and female

Approval Criteria

- Patient > 18 years of age **and**
- Documented adequate therapeutic intervention with 1 or more SSRI antidepressant**,** **or**
- Documented adequate therapeutic intervention with 1 or more SNRI antidepressant **or**
- Documented compliance on current therapy

Denial Criteria

- Claims for patients under 18 years of age (require clinical consultant review)
- Daily dose exceeding 12mg/24hours (require clinical consultant review)
- Lack of adequate initial therapeutic intervention with reference product(s)

References

1. Facts and Comparisons, pg. 1093 - 1094. 2006.
2. USPDI, Micromedex, 2006.
3. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2006.
4. Bristol-Myers Squibb/Somerset Pharmaceuticals, Inc., “Emsam Product Submission”, Princeton, NJ, 08543; April 2006.