



Prior Authorization Approval Criteria

Emsam (selegiline)

Generic name:	Selegiline
Brand name:	Emsam
Medication class:	Antidepressant; monoamine oxidase inhibitor (MAOI)
FDA-approved uses:	Major depression.
Available dosage forms:	6 mg, 9 mg and 12 mg transdermal patches
Usual dose range:	Recommended starting and target dose is 6 mg per 24 hours. May be increased to 12 mg per 24 hours in 3 mg increments made at intervals of no less than 2 weeks.
Duration of therapy:	Indefinite.
Approximate monthly cost:	\$480.00 for all strengths. (based on AWP 2006)

Criteria for use (*bullet points below are all inclusive unless otherwise noted*):

- Clinically diagnosed depression.
- Failed/intolerant to at least one SSRI.
- Failed/intolerant to bupropion.
- Failed/intolerant to venlafaxine.
- Failed/intolerant to at least one TCA.

Cautions:

- Dietary modifications with tyramine restrictions are recommended at dosages exceeding 6 mg per 24 hours.

Contraindications:

- Hypersensitivity to selegiline or to any component of the transdermal system.
- Should not be administered with:
 - Other antidepressants that affect serotonin levels (SSRI's, TCA's, venlafaxine, or bupropion), some analgesics (meperidine, tramadol, methadone, or propoxyphene), dextromethorphan, St. John's wort, mirtazapine, buspirone, or cyclobenzaprine.
 - Agents that can increase risk of hypertensive crisis such as sympathomimetic agents (phenylpropanolamine or some weight loss products)
 - Carbamazepine or oxcarbazepine

Patients should wait one week after stopping any drug that increases serotonin before beginning Emsam treatment to decrease risk of serotonin syndrome. This period should be extended to five weeks for patients switching from fluoxetine (Prozac) to Emsam because of fluoxetine's long half life. Patients should also wait at least two weeks after stopping Emsam to start any drug that is contraindicated with its use.

Not approved if:

- Does not meet the above-stated criteria.
- Have any contraindications to the use of selegiline.
- Being used for Parkinson's disease.

Special considerations:

- Switching patients to and from Emsam will be a problem due to the washout periods.
- Dietary restrictions may be a problem for some patients.
- Currently the oral form of selegiline (Eldepryl) is used in Parkinson's disease. There are no published trials available on the use of Emsam in treating Parkinson's. The 10 mg dose of Eldepryl is not equivalent to available doses of Emsam. The transdermal delivery system targets CNS absorption and bypasses gastric metabolism associated with oral administration and therefore achieves higher plasma levels.
- American Psychiatric Association Guidelines for treatment of depression currently recommend that patients initially receive optimal doses of a first-line treatment. If this fails, patients should be switched to an alternate first-line drug. If patients still do not fully respond, augmentation with combination therapy should be tried before an MAO inhibitor.

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 9/13/06