

| Division: Pharmacy Policy | Subject: State of Florida's Agency for Health Care Administration's |
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| | Prior Authorization Criteria |
| Original Development Date: | May 23, 2014 |
| Original Effective Date: | |
| Revision Date: | June 23, 2015 |
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NAMENDA XR[®] (memantine hydrochloride, extended release)

LENGTH OF AUTHORIZATION: Up to one year

CLINICAL NOTES:

Memantine is an N-methyl-D-aspartate (NMDA) receptor antagonist FDA approved for use in moderate to severe Alzheimer's disease.

INITIAL REVIEW CRITERIA:

Alzheimer's disease:

- Patient must be ≥ 18 years old
- Patient must have a confirmed diagnosis of Alzheimer's Disease (ICD9=331.0)(ICD10=G30*)
- Trial and response to therapy of Namenda IR is required prior to consideration of Namenda XR.

CONTINUATION OF THERAPY

• Patient continues to meet above initial criteria

DOSING & ADMINISTRATION:

- Alzheimer's disease: Initially, 7 mg PO once daily. The dose should be increased in 7 mg increments at minimum intervals of one week up to the recommended target dose of 28 mg once daily. The dose should only be increased if the current dosage level is well tolerated. The maximum daily dose for adult patients with Alzheimer's disease is 28 mg/day.
- When switching from the immediate-release (IR) tablets to the extended-release (ER) capsules, the following conversion is recommended: 10 mg twice daily of the IR tablets should be converted to 28 mg once daily of the ER capsules beginning the day after the last dose of the IR tablet. Patients with severe renal impairment receiving 5 mg twice daily of the IR tablets may be converted to the ER capsules at a dose of 14 mg once daily beginning the day after the last dose of the IR tablet
- Dosing conversions from the immediate release tablets to the extended release capsules are the same as those recommended in adult patients and are as follows:
 - \circ 5mg/day = 7mg XR
 - \circ 10mg/day =14mg XR
 - \circ 15mg/day =21mg XR



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• Dosage Forms:

- Namenda XR 7 mg extended release capsules
- o Namenda XR 14 mg extended release capsules
- Namenda XR 21 mg extended release capsules
- Namenda XR 28 mg extended release capsules
- Namenda XR titration pack (7 each: 7 mg, 14 mg, 21 mg, 28 mg extended release capsules)