

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

\*FHK- Florida Healthy Kids

## Osmolex ER (amantadine extended-release tablets)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

***\*Maryland Medicaid – See State Specific Mandates below***

Medications	Quantity Limit
Osmolex ER (amantadine extended-release tablets)	May be subject to quantity limit

### **APPROVAL CRITERIA**

Requests for Osmolex ER (amantadine extended-release) may be approved if the following criteria are met:

- I. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of amantadine immediate release (AAN 2006, Movement Disorder Society 2011); **AND**
- II. Documentation has been provided for why the extended release agent is clinically necessary and not for convenience; **AND**
- III. Individual is 18 years of age or older; **AND**
- IV. Individual is using to treat one of the following:
  - A. Parkinson's disease; **OR**
  - B. Drug-induced extrapyramidal reactions in adults.

Requests for Osmolex ER (amantadine extended-release) may not be approved for:

- I. Individual has end-stage renal disease (EGFR < 15 mL/min/1.73 m<sup>2</sup>).

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
Maryland Medicaid		Trial of IR amantadine is not required

**Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 14, 2018.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
5. Bhidayasiri R, Fahn S, Weiner WJ, et al. Evidence-based guideline: treatment of tardive syndromes: report of the guideline development subcommittee of the American Academy of Neurology. *Neurology*. 2013;81:463-9. Available at <https://www.aan.com/Guidelines/>. Accessed April 13, 2017.
6. Fox SH, Katzenschlager R, Lim SY, et al. The Movement Disorder Society evidence-based medicine review update: treatments for the motor symptoms of Parkinson's disease. *Mov Disord* 2011; 26(suppl 3):S2-S41.

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