

**Regence BlueCross BlueShield of Oregon • Regence BlueShield  
Regence BlueCross BlueShield of Utah • Regence BlueShield of Idaho  
Independent licensees of the Blue Cross and Blue Shield Association**

**Medication Policy Manual**

**Policy No:** dru153

**Topic:** Luvox<sup>®</sup> CR, fluvoxamine extended-release capsules

**Date of Origin:** May 9, 2008

**Revised/Effective Date:** May 8, 2009

**Next Review Date:** May 2010

**IMPORTANT REMINDER**

This Medical Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of medical policy is to provide a guide to coverage. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

**Description**

Fluvoxamine extended-release (Luvox<sup>®</sup> CR) is a selective serotonin (5-HT) reuptake inhibitor (SSRI) used for the treatment of obsessive-compulsive disorder and social anxiety disorder.

## **Policy/Criteria**

- I.** Most contracts require prior authorization approval of fluvoxamine extended-release capsules prior to coverage. Fluvoxamine extended-release capsules may be considered medically necessary when immediate-release fluvoxamine has been ineffective after at least 12 weeks of treatment or was not tolerated.
  
- II.** Administration, Quantity Limitations, and Authorization Period
  - A.** Regence considers fluvoxamine extended-release capsules to be self-administered medication.
  
  - B.** Authorization may be reviewed at least annually to confirm that current medical necessity criteria are met and that the medication is effective.

## **Position Summary**

- Fluvoxamine extended-release capsules have not been shown to be safer, more effective, or better tolerated than generic fluvoxamine immediate-release tablets in any reliable, published, clinical trials. <sup>[1,2]</sup>

### *Clinical Efficacy*

- The efficacy of fluvoxamine extended-release capsules is similar to fluvoxamine immediate-release capsules for treating obsessive-compulsive disorder (OCD). <sup>[1,2]</sup>
  - \* The efficacy of fluvoxamine extended-release capsules was demonstrated in one 12-week trial with outpatients diagnosed with OCD as defined in DSM-IV.

- \* The efficacy of the immediate-release fluvoxamine tablets in the treatment of OCD was demonstrated in two 10-week, multicenter, parallel-group studies of adult outpatients.
  - \* The effectiveness of fluvoxamine extended-release capsules for long-term use (i.e., for more than 12 weeks) has not been systematically evaluated in placebo-controlled trials.
  - \* Fluoxetine, paroxetine, sertraline, and immediate-release fluvoxamine are indicated for the treatment of OCD, are available generically, and offer the best value for our members.
- Fluvoxamine extended-release capsules have also demonstrated efficacy in patients with social anxiety disorder. <sup>[1,2]</sup>
    - \* The effectiveness of fluvoxamine extended-release capsules in the treatment of social anxiety disorder was demonstrated in two 12-week, multicenter, placebo-controlled studies of adult outpatients with social anxiety disorder (as defined in the DSM-IV). Fluvoxamine extended-release capsules demonstrated statistically significant superiority over placebo at the primary endpoint (Week 12) as assessed by the Liebowitz Social Anxiety Scale (LSAS) total score in both studies.
    - \* The effectiveness of fluvoxamine extended-release capsules in long-term treatment of social anxiety disorder (i.e., for more than 12 weeks) has not been systematically evaluated in adequate and well controlled trials.
    - \* Paroxetine and sertraline are available generically and offer the best value to members for the treatment of social anxiety disorder.

### *Safety*

- Fluvoxamine extended-release capsules and immediate-release tablets are contraindicated in: <sup>[1,2]</sup>
  - \* Concomitant use with alosetron, pimozone, thioridazine, or tizanidine
  - \* Concomitant use with a monoamine oxidase inhibitor (MAOI) or within 14 days following treatment with a MAOI

- Fluvoxamine is a potent inhibitor of several cytochrome P450 isoenzymes that are known to be involved in the metabolism of other drugs such as: CYP1A2 (e.g., warfarin, theophylline, propranolol, tizanidine), CYP2C9 (e.g., warfarin), CYP3A4 (e.g., alprazolam), and CYP2C19 (e.g., omeprazole). In vitro data suggest that fluvoxamine is a relatively weak inhibitor of CYP2D6, but clinically significant drug interactions may occur in patients who are poor metabolizers of CYP2D6. <sup>[1,2]</sup>
- All antidepressants carry risk of side effects.
- Side effect profiles may differ among these products, but overall discontinuation rates from all cause are relatively similar based on individual clinical trials, meta-analysis, and persistency data.
  - \* The vast majority of people who take an antidepressant (90%) experience at least one side effect.
  - \* Most individuals tolerate mild side effects without much difficulty.
  - \* About 20% of individuals discontinue antidepressants because of intolerable side effects.
- Sexual dysfunction is a common side effect among all antidepressants.
  - \* The incidence is reported as anywhere from 5% - 70%. (This difference is likely due to studies that did not measure sexual dysfunction in the same way).
  - \* Bupropion may have less potential for sexual sided effects, but trade-offs include risk of the elevating seizure threshold at higher doses or in patients with history of seizures.
- All antidepressants carry the black box warning for suicidal thoughts in children, adolescents and young adults.
- Of all the antidepressants, only fluoxetine carries FDA labeling for use in pediatric patients for treatment of depression. Fluvoxamine is indicated for the treatment of OCD in patients as young as 8 years.

## References

1. Fluvox CR<sup>®</sup> [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; February 2009.
2. Fluvox<sup>®</sup> [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; February 2009.

Cross References
Lexapro <sup>®</sup> , escitalopram dru148
Effexor XR <sup>®</sup> , venlafaxine extended-release capsules dru146
Savella <sup>®</sup> , milnacaprin dru175
Cymbalta <sup>®</sup> , duloxetine dru147
Pristiq <sup>™</sup> , desvenlafaxine dru154

Codes	Number	Description
N/A		