# Abbreviated Drug Review

| Drug Product | |
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| Belviq (lorcaserin) | Indication not funded |

**Indications**

- Indicated as an adjunct to reduced-calorie diet and increased physical activity in adults who are either obese (BMI ≥30 kg/m2) or overweight (BMI ≥27 kg/m2) with at least one weight-related comorbidity (e.g., type 2 diabetes mellitus [DM], dyslipidemia, or hypertension).

**Dosage**

- 10 mg oral tablet twice daily
- 20 mg film-coated, extended-release tablet once daily
- Discontinuation of lorcaserin is recommended at week 12 if ≥5% of body weight has not been lost.

**Background**

- Although lorcaserin's exact mechanism of action is unknown, this first-in-class agent is believed to curb appetite by selectively activating serotonin 2C receptors on neurons in the hypothalamus which are involved in appetite control.

**Efficacy**

FDA approval of lorcaserin 10 mg twice daily was based on three randomized (1:1), double-blind, placebo-controlled trials: one in adults with inadequately controlled DM (BLOOM-DM) and two in adults without DM (BLOOM and BLOSSOM). All subjects received diet and exercise counseling on the first treatment day and every 4 weeks thereafter. BLOOM and BLOSSOM enrolled subjects who were 18 to 65 years old and either overweight (BMI 27-29.9 kg/m2) with at least one weight-related comorbid condition or obese (BMI 30-45 kg/m2). Most subjects were Caucasian (67%) and approximately 80% were women. BLOOM-DM enrolled subjects who were 21 to 65 years old, had a BMI ≥27 kg/m2, HbA1c of 7-10%, and were taking metformin or a sulfonylurea. Most were Caucasian (61%) and 54% were women. The primary outcome for all of the studies was weight loss at 1 year as assessed by the difference between the lorcaserin groups versus placebo for the following parameters (modified intent-to-treat and last observation carried forward):

| Difference from placebo | BLOOM and BLOSSOM combined (n=3098 lorcaserin; 3038 placebo) | BLOOM-DM (n=251 lorcaserin; 248 placebo) |
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| Percent of patients losing ≥5% body weight | 24.5 (95% CI 22.2 to 26.8, p<0.001) | 21.3 (95% CI 13.8 to 28.9, p<0.001) |
| Percent of patients losing ≥10% body weight | 13.8 (95% CI 12 to 15.5, p<0.001) | 11.9 (95% CI 6.7 to 17.1, p<0.001) |
| Adjusted mean change in weight (kg) | –3.3 (95% CI –3.6 to –2.9, p<0.001) | –3.1 (95% CI –4 to –2.2, p<0.001) |

Attrition rate: 50% BLOOM, 45% BLOSSOM, and 36% BLOOM-DM

**Safety**

**Common adverse reactions (>5%):** Headache, dizziness, fatigue, nausea, dry mouth, and constipation for non-DM patients. Hypoglycemia, headache, back pain, cough, and fatigue for DM patients.
**Contraindications:** Pregnancy or prior hypersensitivity to lorcaserin
**Warnings and precautions:** May increase risk of serotonin syndrome or neuroleptic malignant syndrome-like reactions, valvular heart disease, psychiatric disorders, hypoglycemia, bradycardia, hematological changes, prolactin elevation, and pulmonary hypertension. Monitoring for these adverse effects is recommended. Use with caution in patients with heart failure, bradycardia, history of heart block greater than first degree, predisposition to priapism, moderate renal failure, or severe hepatic impairment. Caution patients about impaired cognitive function and priapism. Use with extreme caution with drugs affecting serotonergic neurotransmitter systems and with CYP2D6 substrates.
**Avoid use in:** Patients with severe renal impairment and pediatric patients.
**Carcinogenesis:** Increased incidence of mammary fibroadenoma was observed in female rats at doses comparable to the human FDA-approved dose.

**Evidence Gaps/Limitations**

No studies found to support evidence for use in the treatment of Oregon Health Plan (OHP) funded conditions or co-morbidities.

**Recommendation**

Restrict use for OHP-funded conditions through Prior Authorization.

**References**

1. Belviq (lorcaserin) [Prescribing Information]. Zofingen, Switzerland: Arena Pharmaceuticals GmbH. December 2014.
2. FDA Center for Drug Evaluation and Research Summary Review. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/022529Orig1s000SumR.pdf. Accessed February 5, 2017.

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