

Clinical Policy: Lorcaserin (Belviq, Belviq XR)

Reference Number: ERX.NPA.90

Effective Date: 12.01.18

Last Review Date: 11.18

[Revision Log](#)

See **Important Reminder** at the end of this policy for important regulatory and legal information.

Description

Lorcaserin (Belviq[®], Belviq XR[®]) is a serotonin 2C receptor agonist.

FDA Approved Indication(s)

Belviq and Belviq XR are indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of:

- 30 kg/m² or greater (obese), or
- 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia.

Limitation(s) of use:

- The safety and efficacy of coadministration of Belviq/Belviq XR with other products intended for weight loss including prescription drugs (e.g., phentermine), over-the-counter drugs, and herbal preparations have not been established.
- The effect of Belviq/Belviq XR on cardiovascular morbidity and mortality has not been established.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions[™] that Belviq and Belviq XR are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Weight Management (must meet all):

1. Member meets one of the following (a or b):
 - a. BMI \geq 30 kg/m²;
 - b. BMI \geq 27 kg/m² with at least one indicator of increased cardiovascular risk (e.g., coronary artery/heart disease, hypertension, dyslipidemia, diabetes, elevated waist circumference) or other obesity-related medical condition (e.g., sleep apnea);
2. Age \geq 18 years;
3. Dose does not exceed 20 mg per day (Belviq: 2 tablets per day; Belviq XR: 1 tablet per day).

Approval duration: 12 weeks

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Weight Management (must meet all):

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. BMI \geq 25 kg/m²;
3. Member meets one of the following (a or b):
 - a. If this is the first renewal request, member has lost \geq 5% of baseline body weight;
 - b. If this is a second or subsequent renewal request, member has lost weight and/or maintained weight loss on therapy;

4. If request is for a dose increase, new dose does not exceed 20 mg per day (Belviq: 2 tablets per day; Belviq XR: 1 tablet per day).

Approval duration:

First reauthorization – 12 weeks

Second or subsequent reauthorization – 6 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BMI: body mass index

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): pregnancy, hypersensitivity
- Boxed warning(s): none reported

Appendix D: General Information

- BMI = $703 \times [\text{weight (lbs)}/\text{height (inches)}^2]$
- Examples of coronary artery/heart disease include: coronary artery bypass graft, angina, history of myocardial infarction or stroke.
- An effective response to a weight loss medication is defined by the Endocrine Society (2015) as weight loss $\geq 5\%$ of body weight at 3 months of therapy. If there is weight loss $< 5\%$ of body weight, the Endocrine Society (as well as Belviq/Belviq XR's prescribing information) recommends discontinuation of the medication.

V. Dosage and Administration

Drug Name	Dosing regimen	Maximum Dose
Lorcaserin (Belviq)	10 mg PO BID	20 mg/day
Lorcaserin (Belviq XR)	20 mg PO QD	20 mg/day

VI. Product Availability

Drug Name	Availability
Lorcaserin (Belviq)	Tablet: 10 mg
Lorcaserin (Belviq XR)	Extended-release tablet: 20 mg

VII. References

1. Belviq, Belviq XR Prescribing Information. Woodcliff Lake, NJ: Eisai, Inc; May 2017. Available at: www.belviq.com. Accessed August 7, 2018.
2. Jensen MD, Ryan DH, Apovian CM, et al. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: a report of the American College of Cardiology/American Heart

Association Task Force on Practice Guidelines and The Obesity Society. Circulation. 2014; 129(suppl 2): S102–S138.

3. Apovian CM, Aronne LJ, Bessesen DH, et al. Pharmacological management of obesity: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2015; 100(2): 42-362.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: adapted from previously approved policy ERX.NPA.12; added coronary artery/heart disease as an example of cardiovascular risk indicator; modified re-auth approval duration to 6 months for second/subsequent requests (first re-auth request remains at 12 weeks); references reviewed and updated.	08.07.18	11.18

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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