envolve Pharmacy Solutions

Clinical Policy: Lorcaserin (Belviq, Belviq XR)

Reference Number: ERX.NPA.90
Effective Date: 12.01.18
Last Review Date: 05.21
Line of Business: Commercial, Medicaid

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/m^2 or greater (obese), or
- 27 kg/m^2 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.

***Eisai Co., Ltd, manufacturer of Belviq, was asked by the FDA to voluntarily withdraw Belviq after a post-market safety trial found an increased occurrence of cancer reported in people who used the product** (*see Appendix E*).

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

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 ≥ 30 kg/m^2;
   b. BMI ≥ 27 kg/m^2 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 ≥ 18 years;
3. Documentation that member is actively enrolled in a weight loss program that involves a reduced calorie diet and increased physical activity adjunct to therapy;
4. Member meets one of the following (a or b):*
   a. Failure of all formulary agents indicated for weight management, unless clinically significant adverse effects are experienced or all are contraindicated;
   b. Failure of all of the following agents indicated for weight management, unless clinically significant adverse effects are experienced or all are contraindicated: Contrave®, Saxenda®, Qsymia®, benzphetamine, phendimetrazine, phentermine, orlistat, diethylpropion;

**Prior authorization may be required*

5. 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 ≥ 25 kg/m^2;
3. Member meets one of the following (a or b):
   a. If this is the first renewal request, member has lost ≥ 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. Documentation that member is actively enrolled in a weight loss program that involves a reduced calorie diet and increased physical activity adjunct to therapy;
5. 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
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Contrave® (bupropion/naltrexone)	8/90 mg PO QAM for one week, then 8/90 mg PO BID for one week; increase dose weekly by one tablet per day until the maintenance dose of two 8/90 mg tablets PO BID is reached (week 4)	32/360 mg/day
Saxenda® (liraglutide)	3 mg SC QD	3 mg/day
benzphetamine (Didrex®, Regimex™)	25-50 mg PO QD-TID	150 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
diethylpropion (Tenuate®)	75 mg CR tablet PO QD	75 mg/day
phendimetrazine (Bontril®, Bontril® SR)	IR: 35-70 mg PO BID-TID SR: 105 mg PO QD	IR: 210 mg/day SR: 105 mg/day
phentermine (Adipex-P®)	37.5 mg PO QD	37.5 mg/day
phentermine/topiramate ER (Qsymia®)	3.75/23 mg PO QD AM for two weeks then increase to 7.5/46 mg QD	15/92 mg/day
orlistat (Xenical®)	120 mg PO TID with each main meal	360 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): pregnancy, hypersensitivity to lorcaserin or to any of the product components
- Boxed warning(s): none reported

Appendix D: General Information

- BMI = 703 x [weight (lbs)/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 ≥ 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.

Appendix E: Withdrawal from Market

- Eisai Co., Ltd, manufacturer of Belviq, was asked by the FDA to voluntarily withdraw Belviq after a post-market safety trial found an increase occurrence of cancer reported in people who used the product.
- FDA believes that the risks of lorcaserin outweigh its benefits.
  - This is based on a completed review of results from a randomized clinical trial assessing safety. In January 2020, FDA announced they were reviewing clinical trial data and alerted the public about a possible risk of cancer associated with lorcaserin based on preliminary analysis of the data. When FDA approved lorcaserin in 2012, they required the drug manufacturer to conduct a randomized, double-blind, placebo-controlled clinical trial to evaluate the risk of cardiovascular problems, which found that more patients taking lorcaserin (n = 462; 7.7 percent) were diagnosed with cancer compared to those taking a placebo, which is an inactive treatment (n = 423; 7.1 percent). The trial was conducted in 12,000 patients over 5 years. A range of cancer types were reported, with several different types of cancers occurring more frequently in the lorcaserin group, including pancreatic, colorectal, and lung.
- Currently FDA recommends patients should stop taking lorcaserin.
  - FDA recommends patients should stop taking lorcaserin and talk to your health care professionals about alternative weight-loss medicines and weight management programs.
- Currently FDA recommends health care professionals stop prescribing and dispensing lorcaserin to patients.
  - Contact patients currently taking lorcaserin, inform them of the increased occurrence of cancer seen in the clinical trial, and ask them to stop taking the medicine. Discuss alternative weight-loss medicines or strategies with your patients.

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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; April 2018. Available at: www.belviq.com. Accessed February 2, 2021.
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
2Q 2019 annual review: no significant changes; references reviewed and updated	02.05.19	05.19
2Q 2020 annual review: added requirement for t/f of all other weight management therapies into criteria; added Appendix B: therapeutic alternatives; added Appendix E: FDA warning statement; references reviewed and updated.	02.26.20	05.20
Criteria added requiring documentation that member is actively enrolled in a weight loss program that involves a reduced calorie diet and increased physical activity adjunct to therapy as per FDA label.	05.26.20	08.20
2Q 2021 annual review: no significant changes; policy to be retired February 2022 after MediSpan obsolete date; references reviewed and updated.	02.24.21	05.21

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.