Clinical Policy: Lorcaserin (Belviq, Belviq XR)

Reference Number: CP.PCH.03
Effective Date: 05.01.17
Last Review Date: 05.19
Line of Business: Commercial, HIM* 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.

**For Health Insurance Marketplace (HIM),* *if request is through pharmacy benefit, Belviq XR is non-formulary and cannot be approved using these criteria; refer to the formulary exception policy, HIM.PA.103.*

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.

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 Centene Corporation® 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. Dose does not exceed 20 mg/day (Belviq: 2 tablets/day; Belviq XR: 1 tablet/day).

Approval duration:
HIM – 12 weeks for Belviq (*Refer to HIM.PA.103 for Belviq XR)*
Commercial – 12 weeks

B. Other diagnoses/indications
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and HIM.PHAR.21 for health insurance marketplace.

II. Continued Therapy

A. Weight Management (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. BMI ≥ 25 kg/m^2;
3. Member is responding positively to therapy as evidenced by 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. If request is for a dose increase, new dose does not exceed 20 mg/day (Belviq: 2 tablets/day; Belviq XR: 1 tablet/day).

Approval duration:
HIM –
First reauthorization: 12 weeks for Belviq (*Refer to HIM.PA.103 for Belviq XR)*
Second or subsequent reauthorization: 6 months for Belviq (*Refer to HIM.PA.103 for Belviq XR)*
Commercial –
First reauthorization: 12 weeks
Second or subsequent reauthorization: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and HIM.PHAR.21 for health insurance marketplace.

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 policies – CP.CPA.09 for commercial and HIM.PHAR.21 for health insurance marketplace 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 to lorcaserin
- 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.

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: https://www.belviq.com/. Accessed February 5, 2019.
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	01.17	05.17
2Q 2018 annual review: no significant changes from previously approved corporate policy; policies combined for Centene Marketplace and Commercial lines of business; HIM: added coronary artery/heart	02.12.18	05.18

Reviews, Revisions, and Approvals	Date	P&T Approval Date
disease as an example of cardiovascular risk indicator; removed requirement for trial of phentermine/phendimetrazine (both stimulants indicated for short-term use only); modified re-auth approval duration to 6 months for second/subsequent requests (first re-auth request remains at 12 weeks); Commercial: removed requirement for documentation of baseline weight; for re-auth: removed "continuation in a formalized weight management program" as this is difficult to verify/enforce; added that BMI must be ≥ 25 kg/m^2; references reviewed and updated.		
2Q 2019 annual review: no significant changes; added contraindications; references reviewed and updated.	02.05.19	05.19

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy: HIM.PA.103.