Clinical Policy: Nebivolol (Bystolic)

Reference Number: HIM.PA.131
Effective Date: 12.01.17
Last Review Date: 11.21
Line of Business: HIM

Revision Log

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

Description

Nebivolol (Bystolic®) is beta-adrenergic blocking agent.

FDA Approved Indication(s)

Bystolic is indicated for the treatment of hypertension, to lower blood pressure.

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.

I. Initial Approval Criteria

A. Hypertension (must meet all)**:**

1. Diagnosis of hypertension;
2. Age ≥ 18 years;
3. Failure of ≥ 2 cardio-selective formulary beta-adrenergic blocking agents (*see Appendix B*) at therapeutic doses, each used for ≥ 4 weeks, unless clinically significant adverse effects are experienced or all are contraindicated;
   **Relevant formulary agents include: acebutolol, atenolol, betaxolol, bisoprolol, metoprolol IR, metoprolol ER*
4. Dose does not exceed 40 mg (2 tablets) per day.

Approval duration: 12 months

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): HIM.PA.154 for health insurance marketplace.

II. Continued Therapy

A. Hypertension (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 40 mg (2 tablets) per day.

Approval duration: 12 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 12 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): HIM.PA.154 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 – HIM.PA.154 for health insurance marketplace or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

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 for all relevant lines of business and may require prior authorization

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Cardio-selective formulary beta-adrenergic blocking agents		
acebutolol (Sectral®)	400 mg PO BID	1,200 mg/day
atenolol (Tenormin®)	25 to 50 mg PO QD	100 mg/day
betaxolol (Kerlone®)	10 mg PO QD	20 mg/day
bisoprolol (Zebeta®)	5 mg PO QD	20 mg/day
metoprolol (Lopressor®, Toprol® XL)	Regular-release: 100 mg PO QD in single or divided doses Extended-release: 25 to 100 mg PO QD	Regular-release: 450 mg/day Extended-release: 400 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):
  - Severe bradycardia
  - Heart block greater than first degree
  - Patients with cardiogenic shock
  - Decompensated cardiac failure
  - Sick sinus syndrome (unless a permanent pacemaker is in place)
  - Patients with severe hepatic impairment (Child-Pugh > B). Bystolic has not been studied in patients with severe haptic impairment, therefore it is not recommended in that population
  - Hypersensitivity to any component of the product
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Hypertension	5 mg PO QD	40 mg/day

VI. Product Availability

Tablets: 2.5 mg, 5 mg, 10 mg, 20 mg

VII. References

1. Bystolic Prescribing Information. Irvine, CA: Allergan USA Inc.; November 2017. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021742s022lbl.pdf. Accessed August 11, 2021.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available at: http://www.clinicalpharmacology-ip.com/. Accessed August 11, 2021.
3. Unger T, Borgi C, Charchar F, et al. 2020 International Society of Hypertension global hypertension practice guidelines. Hypertension 2020; 75(6):1334-1357. https://doi.org/10.1161/HYPERTENSIONAHA.120.15026

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	09.01.17	11.17
4Q 2018 annual review: no significant changes; references reviewed and updated.	07.31.18	11.18
4Q 2019 annual review: no significant changes; references reviewed and updated.	08.13.19	11.19
4Q 2020 annual review: no significant changes; references reviewed and updated.	08.21.20	11.20
Revised dose optimization criteria from maximum 1 tablet to 2 tablets per day.	12.03.20	
4Q 2021 annual review: no significant changes; updated reference for HIM off-label use to HIM.PA.154 (replaces HIM.PHAR.21); references reviewed and updated.	08.11.21	11.21

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.

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