

Drug Policy

Policy: CC	Beta-Blocker Step Therapy Program Preferred Step Therapy Policy	Annual Review Date: 04/20/2023 Last Revised Date: 04/20/2023
----------------------	--	---

OVERVIEW

Beta-blockers can be classified into four pharmacologic subgroups based on their effect on beta and alpha receptors: cardio-selective beta-blockers, nonselective beta-blockers, combined alpha-beta blockers, and beta-blockers with intrinsic sympathomimetic activity (ISA). Cardio-selective beta-blockers are those agents that preferentially block beta-1 receptors over beta-2 receptors. Nonselective beta-blockers block both the beta-1 and beta-2 receptors. Based on mechanism of action, cardio-selective beta-blockers may be safer than nonselective beta-blockers in patients with asthma, chronic obstructive pulmonary disease (COPD), peripheral arterial disease (PAD), and diabetes mellitus who require beta-blocker therapy. However, cardio-selectivity appears to be dose-dependent and at higher doses, cardio-selective agents may lose their selectivity. The dose at which cardio-selectivity is lost varies from patient to patient. Combined alpha-beta blockers non-selectively block beta receptors as well as alpha receptors. Beta-blockers with ISA act as partial beta-receptor agonists and therefore, resting heart rate, cardiac output, and peripheral blood flow are not as reduced.

POLICY STATEMENT

A Preferred step therapy program has been developed to encourage the use of one generic Preferred product prior to the use of a Non-Preferred product. If the Preferred step therapy rule is not met for a Non-Preferred agent at the point of service, coverage will be determined by the Preferred step therapy criteria below. All approvals are provided for 12 months in duration.

Automation: Patients with a history of one Preferred drug within the 130-day look-back period are excluded from step therapy.

Preferred Step A: generic beta-blockers (i.e., acebutolol, atenolol, betaxolol, bisoprolol, carvedilol IR/ER, labetalol, metoprolol tartrate, nadolol, pindolol, propranolol, timolol, metoprolol succinate ER, propranolol ER) and generic beta-blocker/diuretic combinations (i.e., atenolol/chlorthalidone, bisoprolol/HCTZ, metoprolol/HCTZ, propranolol/HCTZ, nadolol/bendroflumethiazide).

Non-Preferred Step A: Some brand name beta-blockers (i.e. Tenormin, Lopressor, Corgard, InnoPran XL, Inderal XL) and brand name beta-blocker combinations (i.e., Tenoretic, Ziac, Lopressor HCT, Dutoprol, Byvalson)

Sotalol Step Therapy Rule

Preferred Step B: generic sotalol

Non-Preferred Step B: brand name Betapace, Betapace AF

Drug Policy

CRITERIA

1. If a patient has tried one generic beta-blocker or generic beta-blocker combination product (Preferred Step A), then approve a brand name beta-blocker or brand name beta-blocker combination product (Non-Preferred Step A).
2. Approve a brand name sotalol product (Non-Preferred Step B) if one of the following conditions are met (a or b):
 - a. If a patient has tried one generic sotalol product (Preferred Step B); OR
 - b. If the strength of the requested Non-Preferred Step B product is not available generically

Initial Approval/ Extended Approval.

A) *Initial Approval:* 1 year (365 days)

B) *Extended Approval:* 1 year (365 days)

Step Therapy Exception Criteria

In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

- A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics **[documentation required]; OR**
- B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent **[documentation required]; OR**
- C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
 1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
 2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as **[documentation required]**. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Drug Policy

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

References

- Saseen JJ, MacLaughlin EJ. Hypertension. In: Dipiro JT, Talbert RL, Yee GC, et al, (Eds). *Pharmacotherapy – A Pathophysiologic Approach*. 8th ed. New York, NY: McGraw-Hill. 2011:101-135.
- Warmack TS, Estes MA, Heldenbrand S, Franks AM. Beta-adrenergic antagonists in hypertension: a review of the evidence. *Ann Pharmacother*. 2009;43(12):2031-2043.
- Ellison KE, Gandhi G. Optimising the use of β -adrenoceptor antagonists in coronary artery disease. *Drugs*. 2005;65(6):787-797.
- Facts and Comparisons® Online. Wolters Kluwer Health, Inc.; 2015. =Accessed on March 12, 2015. Search terms: beta-adrenergic blocking agents (beta-blockers).
- Bystolic™ tablets [prescribing information]. St. Louis, MO: Forest Pharmaceuticals; January 2014.
- Toprol-XL® tablets [prescribing information]. Wilmington, DE: AstraZeneca; May 2014.
- Coreg® tablets [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; July 2011.
- Coreg CR™ capsules [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; May 2014.
- James PA, Oparil S, Carter BL, et al. 2014 evidenced-based guideline for the management of high blood pressure in adults: report from the panel members appointed to the Eighth Joint National Committee (JNC 8). *JAMA*. 2014;311(5):507-520.
- Fihn SD, Gardin JM, Abrams J, et al. 2012 ACCF/AHA/ACP/AATS PcNA/SCAI/STS Guideline for the diagnosis and management of patients with stable ischemic heart disease. Executive summary: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American College of Physicians, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. *Circulation*. 2012;126:3097-3137. Available at <http://circ.ahajournals.org/content/126/25/3097.full.pdf+html>. Accessed on March 12, 2015.
- O’Gara PT, Kushner FG, Ascheim DD, et al. 2013 ACCF/AHA Guideline for the management of ST-elevation myocardial infarction: executive summary: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2013;127:529-555. Available at <http://circ.ahajournals.org/content/127/4/529.full.pdf+html>. Accessed on March 12, 2015.
- Anderson JL, Adams CD, Antman EM, et al. ACC/AHA 2007 guidelines for the management of patients with unstable angina/non-ST-elevation myocardial infarction: executive summary. A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 2002 guidelines for the management of patients with unstable angina/non-ST-elevation myocardial infarction). *Circulation*. 2007;116:803-877. Accessed on March 12, 2015.
- Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2013;128:e240-e327. Available at: <https://circ.ahajournals.org/content/128/16/e240.full.pdf+html>. Accessed on March 12, 2015.
- CIBIS-II Investigators and Committees. The Cardiac Insufficiency Bisoprolol Study II (CIBIS-II): a randomized trial. *The Lancet*. 1999;353:9-13.
- Hjalmarson A, Goldstein S, Fagerberg B, et al. Effects of controlled-release metoprolol on total mortality, hospitalizations, and well-being in patients with heart failure: The Metoprolol CR/XL Randomized Intervention Trial in Congestive Heart Failure (MERIT-HF). *JAMA*. 2000;283(10):1295-1302.
- Packer M, Coats AJS, Fowler MB, et al. Effect of carvedilol on survival in severe chronic heart failure. *N Engl J Med*. 2001;344(22):1651-1658.

This document is subject to the disclaimer found at <https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx> and is subject to change. <https://www.medmutual.com/For-Providers/Policies-and-Standards/Prescription-Drug-Resources.aspx>

Drug Policy

- The CAPRICORN Investigators. Effect of carvedilol on outcome after myocardial infarction in patients with left-ventricular dysfunction: the CAPRICORN randomized trial. *Lancet*. 2001;357:1385-1390.
- Poole-Wilson P, Swedberg K, Cleland JGF, et al. Comparison of carvedilol and metoprolol on clinical outcomes in patients with chronic heart failure in the Carvedilol Or Metoprolol European Trials (COMET): randomized controlled trial. *Lancet*. 2003;362:7-13.
- Van Veldhuisen DJ, Cohen-Solal A, Bohm M, et al, for the SENIORS investigators. Beta-blockade with nebivolol in elderly heart failure patients with impaired and preserved left ventricular injection fraction: data from SENIORS (Study of Effects of Nebivolol Intervention on Outcomes and Rehospitalization in Seniors with Heart Failure). *J Am Coll Cardiol*. 2009;52(23):2150-2158.
- Sotylize™ oral solution [prescribing information]. Atlanta, GA: Arbor Pharmaceuticals and Whitby, ON, Canada: Patheon; October 2014.
- Hemangeol™ oral solution [prescribing information]. Parsippany, NJ: Pierre Fabre; March 2014.
- Betapace®/Betapace® AF tablets [prescribing information]. Zug, Switzerland: made for Covis Pharma; May 2016.

OTHER REFERENCES UTILIZED

- Chatterjee S, Biondi-Zoccai G, Abbate A, et al. Benefits of beta blockers in patients with heart failure and reduced ejection fraction: network meta-analysis. *BMJ*. 2013 Jan 16;346:f55.
- Chen-Scarabelli C, Saravolatz L, Murad Y, et al. A critical review of the use of carvedilol in ischemic heart disease. *Am J Cardiovasc Drugs*. 2012;12(6):391-401.
- Frishman WH, Saunders E. Beta-adrenergic blockers. *J Clin Hypertens (Greenwich)*. 2011;13(9):649-653.
- Go AS, Yang J, Gurwitz JH, et al. Comparative effectiveness of different β -adrenergic antagonists on mortality among adults with heart failure in clinical practice. *Arch Intern Med*. 2008;168(22):2415-2421.
- Munzel T, Gori T. Nebivolol. The somewhat different β -adrenergic receptor blocker. *J Am Coll Cardiol*. 2009;54(16):1491-1499.
- Kamp O, Metra M, Bugatti S, et al. Nebivolol. Haemodynamic effects and clinical significance of combined β -blockade and nitric oxide release. *Drugs*. 2010;71(1):41-56.
- Ram CVS. Beta-blockers in hypertension. *Am J Cardiol*. 2010;106:1819-1825.
- Wiysonge CS, Bradley HA, Volmink J, et al. Beta-blockers for hypertension. *Cochrane Database Syst Rev*. 2012 Nov 14;11:CD002003.