



Louisiana

Beta Adrenergic Antagonists and Beta Adrenergic Antagonist/Diuretic Combination Drugs

Policy # 00338

Original Effective Date: 01/09/2013

Current Effective Date: 03/14/2022

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

For Patients With "Step Therapy" (generic before brand) ONLY:

Based on review of the available data, brand name oral beta adrenergic antagonists (beta blockers) and brand name beta adrenergic antagonist/diuretic combination drugs, including, but not limited to Toprol XL[®]† (metoprolol succinate), Coreg CR[®]† (carvedilol phosphate), Bystolic[®]† (nebivolol), Innopran XL[®]† (propranolol), Inderal XL[®]† (propranolol), Tenoretic[®]† (atenolol/chlorthalidone), Lopressor HCT[®]† (metoprolol tartrate/hydrochlorothiazide), Kaspargo[™]† (metoprolol succinate), and Dutoprol[®]† (metoprolol succinate/hydrochlorothiazide) may be considered **eligible for coverage**** when one of the below patient selection criteria is met:

Patient Selection Criteria:

Coverage eligibility will be considered for brand name oral beta adrenergic antagonists and brand name oral beta adrenergic antagonist/diuretic combination drugs when one of the following criteria is met:

- The patient has tried and failed ONE generic oral beta adrenergic antagonist or beta adrenergic antagonist/diuretic combination drug (e.g. metoprolol succinate ER, carvedilol, bisoprolol/hydrochlorothiazide, or metoprolol/hydrochlorothiazide); OR
- There is clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient.

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of brand name oral beta adrenergic antagonists and brand name oral beta adrenergic antagonist/diuretic combination drugs when patient selection criteria are not met or for usage not included in the above patient selection criteria to be **not medically necessary**.**

For Patients With “Prior Authorization” ONLY:

Based on review of available data, the Company may consider Innopran XL (propranolol), Inderal XL (propranolol), or Kapsargo (metoprolol succinate) to be **eligible for coverage**** when the patient selection criteria are met:

Patient Selection Criteria

Coverage eligibility will be considered for Innopran XL (propranolol), Inderal XL (propranolol), or Kapsargo (metoprolol succinate) when the patient selection criteria are met for the respective drug:

- For Innopran XL or Inderal XL requests ONLY:
 - Patient has tried and failed (e.g. intolerance or inadequate response) at least TWO generic beta adrenergic antagonists (e.g., metoprolol succinate, propranolol ER, acebutolol, atenolol, betaxolol, bisoprolol, metoprolol tartrate, nadolol, pindolol, propranolol, sotalol, timolol) unless there is clinical evidence or patient history that suggests the use of the required drugs will be ineffective or cause an adverse reaction to the patient.
- For Kapsargo requests ONLY:
 - Patient has tried and failed (e.g. intolerance or inadequate response) at least TWO generic beta adrenergic antagonists (e.g., metoprolol succinate, propranolol ER, acebutolol, atenolol, betaxolol, bisoprolol, metoprolol tartrate, nadolol, pindolol, propranolol, sotalol, timolol) unless there is clinical evidence or patient history that suggests the use of the required drugs will be ineffective or cause an adverse reaction to the patient; OR
 - BOTH of the following:
 - Patient is unable to swallow tablets; AND
 - Patient is not taking any medication in tablet or capsule form.

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Innopran XL (propranolol), Inderal XL (propranolol), and Kaspargo (metoprolol succinate) when patient selection criteria are not met or for usage not included in the above patient selection criteria to be **not medically necessary**.**

For Patients With BOTH “Prior Authorization” AND “Step Therapy”:

Based on review of the available data, brand name oral beta adrenergic antagonists (beta blockers) and brand name beta adrenergic antagonist/diuretic combination drugs, including, but not limited to Toprol XL (metoprolol succinate), Coreg CR (carvedilol phosphate), Bystolic (nebivolol), Innopran XL (propranolol), Inderal XL (propranolol), Tenoretic (atenolol/chlorthalidone), Lopressor HCT (metoprolol tartrate/hydrochlorothiazide), Kaspargo (metoprolol succinate), and Dutoprol (metoprolol succinate/hydrochlorothiazide) may be considered **eligible for coverage**** when one of the below patient selection criteria is met:

Patient Selection Criteria

Coverage eligibility will be considered for brand name oral beta adrenergic antagonists and brand name oral beta adrenergic antagonist/diuretic combination drugs when all of the specific drug's criteria are met for the requested drug:

- For Innopran XL or Inderal XL requests ONLY:
 - Patient has tried and failed (e.g. intolerance or inadequate response) at least TWO generic beta adrenergic antagonists (e.g., metoprolol succinate, propranolol ER, acebutolol, atenolol, betaxolol, bisoprolol, metoprolol tartrate, nadolol, pindolol, propranolol, sotalol, timolol) unless there is clinical evidence or patient history that suggests the use of the required drugs will be ineffective or cause an adverse reaction to the patient.
- For Kaspargo requests ONLY:
 - Patient has tried and failed (e.g. intolerance or inadequate response) at least TWO generic beta adrenergic antagonists (e.g. metoprolol succinate, propranolol ER, acebutolol, atenolol, betaxolol, bisoprolol, metoprolol tartrate, nadolol, pindolol, propranolol, sotalol, timolol) unless there is clinical evidence or patient history that suggests the use of the required drugs will be ineffective or cause an adverse reaction to the patient; OR

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- BOTH of the following:
 - Patient is unable to swallow tablets; AND
 - Patient is not taking any medication in tablet or capsule form.
- For all other brand beta adrenergic antagonist products:
 - The patient has tried and failed ONE generic oral beta adrenergic antagonist or beta adrenergic antagonist/diuretic combination drug (e.g. metoprolol succinate ER, carvedilol, bisoprolol/hydrochlorothiazide, or metoprolol/hydrochlorothiazide); or
 - There is clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of brand name oral beta adrenergic antagonists and brand name oral beta adrenergic antagonist/diuretic combination drugs when patient selection criteria are not met or for usage not included in the above patient selection criteria to be **not medically necessary**.**

Background/Overview

Oral beta adrenergic receptor antagonists (beta blockers) and beta blocker/diuretic combination drugs are used for various indications including hypertension, heart failure, and myocardial infarctions.

Rationale/Source

The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests the drug will be ineffective or cause an adverse reaction to the patient. Based on a review of the data, in the absence of the above mentioned caveat, there is no advantage of using a brand name beta adrenergic receptor antagonist (beta-blocker) or brand name beta blocker/diuretic combination drug over the available generic beta blockers or generic beta blocker/diuretic combination drugs. Generic drugs are considered to have equal bioavailability and efficacy in comparison to brand name drugs.

References

1. Express Scripts Beta-Blocker Step Therapy Policy. 09/19/2012.

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2. Saseen JJ, MacLaughlin EJ. Hypertension. In: Dipro JT, Talbert RL, Yee GC, et al, (Eds). *Pharmacotherapy – A Pathophysiologic Approach*. 8th ed. New York, NY: McGraw-Hill. 2011:101-135.
3. 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.
4. Ellison KE, Gandhi G. Optimising the use of β -adrenoceptor antagonists in coronary artery disease. *Drugs*. 2005;65(6):787-797.
5. Chobanian AV, Bakris GL, Black HR, et al. Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. *JAMA*. 2003;289(19):2560-72. Available at: <http://www.nhlbi.nih.gov/guidelines/hypertension/>.
6. Antman EM, Anbe DT, Armstrong PW, et al. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction. *Circulation*. 2004;110(9):e82-292.
7. Antman EM, Hand M, Armstrong, PW, et al. 2007 focused update of the ACC/AHA 2004 guidelines for the management of patients with ST-elevation myocardial infarction. A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. at <http://circ.ahajournals.org/cgi/reprint/CIRCULATIONAHA.107.188209>
8. 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. at <http://circ.ahajournals.org/cgi/reprint/CIRCULATIONAHA.107.181940>
9. 2005 Writing Committee Members, Hunt SA, Abraham WT, Chin EH, et al. 2009 focused update incorporated into the ACC/AHA guidelines for the diagnosis and management of heart failure in adults: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines: developed in collaboration with the International Society for Heart and Lung Transplantation. *Circulation*. 2009;119:e391-e479. Accessed 3/5/2012 at <http://circ.ahajournals.org/cgi/reprint/CIRCULATIONAHA.109.192065>
10. CIBIS-II Investigators and Committees. The Cardiac Insufficiency Bisoprolol Study II (CIBIS-II): a randomized trial. *The Lancet*. 1999;353:9-13.
11. 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.

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12. 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.
13. 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.
14. 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.
15. Flather MD, Shibata MC, Coats AJS, et al, on behalf of the SENIORS Investigators. Randomized trial to determine the effect of nebivolol on mortality and cardiovascular hospital admission in elderly patients with heart failure (SENIORS). *Eur Heart J.* 2005;26:215-225.
16. Kapsargo [package insert]. Sun Pharmaceutical. Cranbury, NJ. Jun 2018.

Policy History

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- | | |
|------------|---|
| 01/03/2013 | Medical Policy Committee review |
| 01/09/2013 | Medical Policy Implementation Committee approval. New policy. |
| 02/19/2013 | Format revision. Coding section removed. |
| 01/09/2014 | Medical Policy Committee review |
| 01/15/2014 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 02/05/2015 | Medical Policy Committee review |
| 02/18/2015 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 02/04/2016 | Medical Policy Committee review |
| 02/17/2016 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 02/02/2017 | Medical Policy Committee review |
| 02/15/2017 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 02/01/2018 | Medical Policy Committee review |

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02/21/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

09/06/2018 Medical Policy Committee review

09/19/2018 Medical Policy Implementation Committee approval. Added brand Innopran XL and Inderal XL to step 2. Also separated out into step, step/PA, and PA only to address the PA added to Innopran XL and Inderal XL.

02/07/2019 Medical Policy Committee review

02/20/2019 Medical Policy Implementation Committee approval. Added new drug, Kapsargo to the policy with PA criteria for members with PA.

02/06/2020 Medical Policy Committee review

02/12/2020 Medical Policy Implementation Committee approval. No change to coverage.

02/04/2021 Medical Policy Committee review

02/10/2021 Medical Policy Implementation Committee approval. No change to coverage.

02/03/2022 Medical Policy Committee review

02/09/2022 Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 02/2023

****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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