

Drug and Biologic Coverage Policy



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Coverage Policy Number IP0461

Beta Blockers

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for propranolol extended-release capsule (**InnoPran XL**[®]).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage varies across plans and requires the use of preferred products. Refer to the customer's benefit plan document for coverage details.

The product in the table below is considered medically necessary when the following are met:

Employer Group Non-Covered Products and the Preferred Covered Alternatives:

Non-Covered Product	Criteria
InnoPran XL (propranolol) extended-release 80 gm and 120 mg capsules	There is documentation the individual is intolerant to propranolol extended-release capsules (80 mg and 120 mg).

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

InnoPran XL (propranolol extended-release capsule) is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months
 Reauthorization approval duration: up to 12 months

Background

OVERVIEW

Beta-blockers can be classified into four pharmacologic subgroups based on their effect on beta and alpha receptors: cardioselective beta-blockers, nonselective beta-blockers, combined alpha-beta blockers, and beta-blockers with intrinsic sympathomimetic activity (ISA). Cardioselective 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, cardioselective beta-blockers may be safer than nonselective beta-blockers in patients with asthma, chronic obstructive pulmonary disease, peripheral arterial disease, and diabetes mellitus who require beta-blocker therapy. However, cardioselectivity appears to be dose-dependent and at higher doses, cardioselective agents may lose their selectivity. The dose at which cardioselectivity is lost varies from patient to patient. Combined alpha-beta blockers nonselectively 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.¹⁻³ Table 1 classifies the beta-blockers by subgroup.

Table 1. Beta-Blockers by Pharmacologic Subgroup.¹⁻⁴

Cardioselective beta-blockers	Nonselective beta-blockers	Combined alpha-beta blockers	Beta blockers with ISA
atenolol betaxolol bisoprolol metoprolol tartrate metoprolol succinate XL nebivolol ^{++†}	nadolol propranolol propranolol extended-release [‡] timolol	carvedilol carvedilol extended-release [°] labetalol	acebutolol penbutolol [^] pindolol

ISA – Intrinsic sympathomimetic activity; + May have vasodilatory properties; ° In extensive metabolizers and at doses less than or equal to 10 mg nebivolol is preferentially beta₁ selective. In poor metabolizers and at higher doses, it is nonselective; † Available as Bystolic; ^ Available as a generic and as InnoPran XL; ° Available as Coreg CR; ^ Available as Levatol.

InnoPran XL is indicated for the treatment of hypertension, to lower blood pressure⁵.

References

1. MacLaughlin EJ, Saseen JJ. Hypertension. In: Dippiro JT, Talbert RL, Yee GC, et al, (Eds). *Pharmacotherapy – A Pathophysiologic Approach*. Eleventh Edition (11e). New York, NY: McGraw-Hill Education. Copyright 2019.
2. 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.
3. Ellison KE, Gandhi G. Optimising the use of β -adrenoceptor antagonists in coronary artery disease. *Drugs*. 2005; 65(6):787-797.
4. Facts and Comparisons® Online. Wolters Kluwer Health, Inc.; 2022. Available at <http://efactsonline.com>. Accessed on April 29, 2021. Search terms: beta-adrenergic blocking agents (beta-blockers).
5. InnoPran XL® extended-release capsules [prescribing information]. Vandalia, Ohio: Adare Pharmaceuticals, Inc; August 2021.

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