



Preferred Drug List

NEW DRUG REVIEW

Proprietary Name: Bystolic™

Common Name: Nebivolol

PDL Category: Beta Blockers – Cardio Selective

<u>Comparable Products</u>	<u>Preferred Drug List/ Recommended Drug List Status</u>
Toprol XL® (metoprolol ER)	Preferred

Summary

Indications and Usage: Hypertension

Mechanism of Action: Lowers blood pressure by antagonizing β_1 and β_2 adrenergic receptors. At doses of 10mg or less, nebivolol is more β_1 selective and reduces total peripheral resistance via vasodilation.

Dosage Forms: Tablets; 2.5mg, 5mg, 10mg

Recommended Dosage: Initiate 5mg once daily; may titrate every two weeks up to 40mg

Common Adverse Drug Reactions: Dizziness, fatigue, headache, diarrhea, nausea

Contraindications: Hypersensitivity to nebivolol or any component of the compound, severe bradycardia, first degree heart block or greater, cardiogenic shock, sick sinus syndrome, decompensated cardiac failure, severe hepatic impairment

Manufacturer: Forest Laboratories, Inc. & Mylan Inc.

Analysis: Bystolic™ is a beta adrenergic blocker that has been used in Europe for several years which has just now been approved by the FDA. At doses of 10mg/day or less, Bystolic™ is β_1 selective and offers the added benefit of reducing total peripheral resistance via vasodilation. A post marketing surveillance study published in an Indian medical journal called the EVOLVE PMS study, examined 301 patients treated with nebivolol. After one month of therapy, there was a mean 14.32% systolic blood pressure reduction from baseline and a mean 13.9% diastolic blood pressure reduction from baseline. Additionally, 82.33% of the patients achieved JNC VII goals after one month of therapy on nebivolol. Nebivolol is unique in that its side effect profile is boasted as more favorable than that other beta blockers with only 7-9% of patients reporting headache, 2-5% of patients reporting fatigue, and 2-4% of patients reporting dizziness in clinical trials. By comparison, 5-8% of patients reported headache while taking carvedilol in the COPERNICUS trial, 24% of patients reported fatigue on carvedilol in the same trial, and 1.8% of patients reported dizziness on extended release metoprolol in the MERIT-HF Study. Early clinical trials published in the European Journal of Pharmacology also suggest that nebivolol may offer additional vascular protection for treating diabetes associated with hypertension. To date, no head-to-head comparisons of clinical efficacy or side effect profiles have been published. Currently, other beta blockers appear on the Preferred Drug List as more cost effective alternatives to Bystolic™ which are equally effective at lowering blood pressure.

IME Recommendation:

<input type="checkbox"/> Preferred Drug	<input type="checkbox"/> Recommended Drug
<input checked="" type="checkbox"/> Non-Preferred Drug	<input type="checkbox"/> Non-Recommended Drug
<input type="checkbox"/> Preferred Drug with Conditions	