

Blue Cross and Blue Shield of Vermont and The Vermont Health Plan Prior Approval Guidelines Bystolic™ (nebivolol)

DESCRIPTION: The active ingredient of Bystolic™ nebivolol, is a β -adrenergic blocking agent. Nebivolol is preferentially β_1 - selective. Nebivolol lacks intrinsic sympathomimetic and membrane stabilizing activity at therapeutically relevant concentrations. At clinically relevant doses, Nebivolol does not demonstrate alpha1-adrenergic receptor blockade activity. Various metabolites, including glucuronides contribute to beta-blocking activity.

INDICATION(S): Nebivolol is indicated for the treatment of hypertension.

REASONS FOR PA: Cost Potential for misuse Toxicity

CRITERIA for APPROVAL:

1. Patient has been diagnosed with hypertension.
2. Is patient greater than 18 years of age
3. Has patient tried and failed two generic beta selective adrenergic blocking agents?

REASONS for DENIAL of BENEFIT:

1. Patient has a known hypersensitivity to Bystolic™ nebivolol or any of its components.
2. Patient has severe bradycardia, heart block greater than first degree, cardiogenic shock, decompensated cardiac failure, sick sinus syndrome, or severe hepatic impairment (Child-Pugh >B)?
3. Patient does not meet above criteria.

RENEWAL CRITERIA: Review of past 12 months demonstrates clinical improvement, indicated by improved hemodynamic parameters.

BENEFIT APPROVAL: Initial approval period: 12 months.
Renewal approval period: 24 months.

References:

1. Bystolic™ nebivolol Prescribing Information, Forest Pharmaceuticals Inc. December 2007