

AREA PRESCRIBING COMMITTEE – Birmingham, Sandwell, Solihull and environs

Decision Making Support Tool

The following document supports the committee to consider formulary applications against defined criteria.

Formulary application reference:		APCBSSE/0056
Drug name and formulations:		Nebivolol 5 mg tablets
Criteria	Example	Committee Consensus
Patient Safety	<i>Potential for abuse, toxicity, significant drug interactions</i>	No different to other beta blocker. Potential for confusion if dose is half a tablet. Increased risk of bradycardia and adverse effects if taken with other medicines which inhibit CYP2D6 isoenzyme. SPC does not mention interaction with PDE5 inhibitors such as sildenafil.
Clinical effectiveness	<i>Established licensed product</i>	No direct comparison with bisoprolol. Evidence provided is not in patient population targeted.
Strength of evidence		Evidence of benefit or neutral effect on erectile dysfunction (ED) is weak.
Cost effectiveness or resource impact	£	Based on July 2017 Drug Tariff, 28 days' supply of nebivolol 5mg costs £1.26; this increases to £27.62 for 2.5mg tablets. Commissioners cannot guarantee that only 5mg tablets will be used. Potential for much larger cohort of patients to be prescribed this drug which will have significant resource impact. Prescribing generic sildenafil to patients with ED due to beta blockers would be better use of resources.
Place of therapy relative to available treatments	<i>1/2nd tier</i>	Fourth or fifth line. Already 8 beta blockers on formulary. RAG status needs careful consideration.
National guidance and priorities	<i>NICE, MTRAC</i>	NICE CG 127 (2011) recommends the use of beta-blockers as an add-on in uncontrolled hypertension once a step-wise approach has been followed. However, beta-blockers may be used as first line for the following cohort: a) women who wish to or are highly likely to become pregnant, b) those who are under the age of 55 years and/or c) are intolerant to or contra-indicated for treatment with ACE-I or

		Angiotensin II Receptor Antagonists. NICE make no specific recommendations as to which beta-blocker to prescribe other than to choose one which is generic, cost effective and may be taken once-daily.
Local health priorities	<i>CCG views</i>	Primary care members are very concerned with keeping patients on the 5mg formulation. This does not offer as wide dose range as existing formulary options.
Equity of access	<i>Equality assessment</i>	N/A
Stakeholder views	<i>Define wider groups to be engaged</i>	The three local acute trusts support the application for nebivolol. A Red RAG status would incur significant costs around out-patient attendance to obtain further supplies which would limit the number of patients CCGs can fund.
Implementation requirements	<i>Requires, RICAD ESCA etc.</i>	Depends on RAG status if approved.

Decision Summary

Resubmission is recommended to complete the information to enable a decision:	Invite a resubmission of the application in the future with clearly defined patient cohort.
Not approved and rationale:	Not approved. Rationale: feedback from the applicant does not enable the APC to make a decision as the patient cohort has not been clearly defined.
Formulary status (RAG) and rationale	BLACK (Non-formulary)
Implementation requirements:	
Implementation monitoring:	