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/00003
Drug name and formulations:	Brimonidine 3mg/g gel (**Mirvaso ®**)

Criteria	***Example***	**Committee Consensus**
Patient Safety	*Potential for abuse, toxicity, significant drug interactions*	The APC considered that the clinical data presented offered only limited long term safety information; however the adverse effects reported in trials were transient and mild. It was highlighted that there has been a lack of research into drug interactions with other topical products used in the management of rosacea and that this product had a long list of cautions for use.
Clinical effectiveness	*Established licensed product*	The APC noted that evidence for effectiveness has been demonstrated against placebo. Benefits were seen in a controlled cohort of patients with moderate to severe facial erythema of rosacea but only whilst on active treatment. It has been shown to reduce erythema through its pharmacological actions but it is not curative. It was noted that the licenced indication does not distinguish the severity. The study size of 1200 was deemed reasonable
Strength of evidence		Moderate- two relatively short pivotal studies: randomised, double-blind, vehicle controlled parallel group studies; and one supportive open-label, long term study.
Cost effectiveness or resource impact	*£*	The APC noted that the costs, if used for a small cohort of patients in accordance with trial cohorts, are not that high. Concerns were noted about primary care prescribing

		extending beyond the identified niche of patients thus leading to higher spend.
Place of therapy relative to available treatments	*1/2nd tier*	Second tier- for patients unresponsive to other treatments with severe erythema of rosacea
National guidance and priorities	*NICE, MTRAC*	NICE guidance is not expected for this treatment Scottish Medicines Consortium: advice is not expected until January 2015
Local health priorities	*CCG views*	Low commissioning priority
Equity of access	*Equality assessment*	N/A
Stakeholder views	*Define wider groups to be engaged*	N/A
Implementation requirements	*Requires, RICAD ESCA etc.*	Trusts to implement their own methods to manage use of this product for severe patients. Not suitable to refer to Primary Care

Decision Summary

Resubmission is recommended to complete the information to enable a decision:	
Not approved and rationale:	
Formulary status (RAG) and rationale	Approved as RED formulary status, for specialist dermatologists to use in specific niche of patients with severe erythema of rosacea, otherwise untreatable. It is up to individual trusts to consider use within their organisation.
Implementation requirements:	Trusts to make their own internal recommendation for initiation, continuation and discontinuation of treatment, without the need for a formal RICaD. It is not suitable to refer to Primary Care.
Implementation monitoring:	CCGs to monitor requests for prescribing in Primary Care. Trusts would be able to present to APC for review in the future (Minimum 12 months from application)