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/0034
Drug name and formulations:		Budesonide MMX (Cortiment®)
Criteria	***Example***	**Committee Consensus**
Patient Safety	*Potential for abuse, toxicity, significant drug interactions*	Trial data shows that the incidence of adverse events was similar with budesonide and placebo. Budesonide has a similar safety profile to other oral steroids, but anecdotal evidence suggests it is better tolerated.
Clinical effectiveness	*Established licensed product*	In two 8-week studies, budesonide MMX statistically significantly increased rates of combined clinical and endoscopic remission in adults with mild to moderate ulcerative colitis compared with placebo. However the effect size was small and the clinical relevance of the improvements is unclear. There was no statistically significant difference between budesonide MMX and placebo for clinical improvement and endoscopic improvement at week 8 (secondary end points).
Strength of evidence		No evidence comparing to active treatment. Small clinical trials.
Cost effectiveness or resource impact	*£*	SMC concluded the economic case has been demonstrated. Suggestion made that this could avoid hospital admission for IV steroids, but no data as yet. More expensive than oral prednisolone
Place of therapy relative to available treatments	*1/2nd tier*	Second line after failed trial of oral prednisolone, to avoid use of IV steroids.
National guidance and priorities	*NICE, MTRAC*	No MTRAC, NICE TA October 2016: SMC accepted for restricted use within NHS Scotland
Local health priorities	*CCG views*	Need data as to whether hospital admissions are prevented.
Equity of access	*Equality assessment*	N/A
Stakeholder views	*Define wider groups to be engaged*	N/A

Implementation requirements	*Requires, RICAD ESCA etc.*	N/A

Decision Summary

Resubmission is recommended to complete the information to enable a decision:	
Not approved and rationale:	
Formulary status (RAG) and rationale	RED Initiation and maintenance of prescribing by Specialists only. **Rationale**: As yet little information to confirm admissions would be avoided. The APC would wish to see this data in the form of case reports, tracking the patients' journey. Would also require further clarification around discontinuation as the SmPC recommends it may be useful to gradually reduce the dose at the discretion of the treating physician. **Review in 12 months.**
Implementation requirements:	
Implementation monitoring:	