

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/00021
Drug name and formulations:	Linaclotide (Constella [®] ▼)

Criteria	Example	Committee Consensus
Patient Safety	<i>Potential for abuse, toxicity, significant drug interactions</i>	Most common side effect is diarrhoea (occurs in <20% pts). In rare and more severe cases, this may lead to hypokalaemia, dehydration, dizziness and hypostatic hypotension. Risk of delayed diagnosis.
Clinical effectiveness	<i>Established licensed product</i>	Large placebo response was noted. 55% of treatment group vs. 42% of placebo group.
Strength of evidence		Short randomised control trials. No head to head trials.
Cost effectiveness or resource impact	£	Cost effective, lower cost than prucalopride and lubiprostone – but more expensive than all the other alternative agents.
Place of therapy relative to available treatments	<i>1/2nd tier</i>	For patients who have not responded adequately to or cannot tolerate all other suitable treatment options, but before other agents with higher costs.
National guidance and priorities	<i>NICE, MTRAC</i>	NICE Clinical Guideline 61 but no NICE TA. MTRAC has considered it suitable for prescribing in Primary care, but evidence was considered relatively weak and place in therapy to be low.
Local health priorities	<i>CCG views</i>	Alternative to the more expensive options such prucalopride and lubiprostone. Patients should be followed up 3 months after taking linaclotide.
Equity of access	<i>Equality assessment</i>	N/A

Stakeholder views	<i>Define wider groups to be engaged</i>	None
Implementation requirements	<i>Requires, RICAD ESCA etc.</i>	Requires a RICaD

Decision Summary

Resubmission is recommended to complete the information to enable a decision:	
Not approved and rationale:	
Formulary status (RAG) and rationale	AMBER with a RICaD. Similar RAG rating to other agents with novel mechanisms of action.
Implementation requirements:	
Implementation monitoring:	