South Staffordshire Area Prescribing Group

Rationale for Initiation, Continuation and Discontinuation (RICaD)

Lubiprostone (Amitiza®)

For the treatment of Chronic Idiopathic Constipation(NICE TA 318)

This document is recommended by the South Staffordshire Area Prescribing Group for selected medicines that do not require an Effective Shared Care Arrangement but where GPs may wish for reassurance that certain guidance(usually NICE) is being followed. It is intended for completion by specialists in order to give Primary Care prescribers a clear indication of the reason for recommending the medication together with suggested criteria for its subsequent continuation or discontinuation. This RICaD should be provided as a supplement to the specialist's clinical letter

PID		**Name**	
DOB		**Patient address**	

GP	**Dr**	**GP address**	

Rationale for Choice – to be completed by the specialist and sent to the GP with clinic letter.

1.1 Lubiprostone is recommended as an option for treating chronic idiopathic constipation, that is, for adults in whom treatment with at least 2 laxatives from different classes, at the highest tolerated recommended doses for at least 6 months, has failed to provide adequate relief and for whom invasive treatment for constipation is being considered.

1.2 If treatment with lubiprostone is not effective after 2 weeks, the person should be re-examined and the benefit of continuing treatment reconsidered.

1.3 Lubiprostone should only be prescribed by a clinician with experience of treating chronic idiopathic constipation, who has carefully reviewed the person's previous courses of laxative treatments specified in 1.1.

Lubiprostone will be considered as an option for a similar group of patients for which prucalopride is also supported by NICE. Prucalopride however is only supported for use in women.

	Specialists please complete all shaded areas as appropriate
Relevant Diagnosis:	
Agreed Indication(s) for inclusion in the Formulary:	Only for patients meeting all relevant NICE criteria
Reason why Lubiprostone has been chosen in preference to drugs without Formulary restrictions:	The patient meets the NICE criteria **Please cross box** **1** Patient is suffering from chronic Idiopathic constipation ☐ **2** The patient has used the following 2 laxative drugs from different classes for a period of 6 months at maximum tolerated doses: ☐ …… And ……. **3** Invasive treatment is being considered if this treatment fails. ☐ **4** The patient has already been prescribed treatment for 2 weeks and has obtained sufficient benefit to continue. ☐ **5** Please initiate treatment for a period of 2 weeks before assessing response. ☐ Details of other medical problems or co-morbidities Details of other concurrent therapies:

I confirm that this patient is eligible to receive lubiprostone under the above restrictions.	
Specialist (please print and sign)	
Contact details and date	

Guidance on initiation and titration

Initiation dose:	**Lubiprostone is supplied in packs of 28 and 56.** **The 28 pack should be supplied to assess response for a period of 2 weeks. Those patients who are suitable to continue should then be prescribed the 56 pack.** **The dose is 24micrograms twice daily**
Additional info:	SPC can be accessed at http://emc.medicines.org.uk
Monitoring:	

Criteria for Assessment and Continuation

Assessment of Efficacy	
Date	After two weeks initially.
Location	GP practice/Specialist
Method	
Continuation Criteria	Lubiprostone should only be continued in patients tolerating and benefiting from treatment after 2 weeks from initiation
Discontinuation Criteria	Insufficient or Loss of benefit, or adverse effects (see below)
Follow up action	

Adverse effects:
For full information please refer to the manufacturers SPC : http://emc.medicines.org.uk

- Nausea is the most common adverse effect- experienced by ~23% of patients in trials, many however only had a single episode of nausea and withdrawals due to nausea only amounted to 4% of patients. Administration with food has been shown to reduce nausea.
- Diarrhoea was also classed as a common event- experienced by 8.3% of patients. Abdominal pain, flatulence and distension are also reported.
- In the clinical studies and in post-marketing surveillance, **Dyspnoea** has been reported, usually with 30-60 minutes of taking the dose.
- Doses should be reduced in patients with moderate to severe hepatic failure in accordance with SPC.