Rationale for Initiation, Continuation and Discontinuation (RICaD)

Eluxadoline▼

For treating irritable bowel syndrome with diarrhoea (NICE TA 471)

This document supports the use and transfer of an agent which is classified as **AMBER**.
It is intended for completion by specialist in order to give Primary Care prescribers a clear indication of the reason for recommending an **AMBER** 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.

Patient details		**GP details**		**Specialist details**	
Name		**GP name**	**Dr**	**Specialist name**	
NHS Number		**GP address**		**I confirm that this patient is eligible to receive eluxadoline under the restrictions listed below**	
DOB				**Signature**	
Patient address				**Date**	
				Contact details	

Rationale for Choice

Relevant Diagnosis:	Irritable bowel syndrome with diarrhoea in adults (NICE TA 471)				
MHRA Drug Safety alert (Dec 2017)	Advice for healthcare professionals: • eluxadoline (Truberzi®▼), licenced for irritable bowel syndrome with diarrhoea, should be initiated and supervised by a specialist physician experienced in diagnosis and management of gastrointestinal disorders. • **do not** use in patients without a gallbladder or in patients with known or suspected biliary tree or pancreatic duct obstruction (e.g. gallstones, tumour, periampullary duodenal diverticulum) or sphincter of Oddi disease or dysfunction. • tell patients to avoid drinking alcohol during treatment with eluxadoline. • inform patients about symptoms suggestive of pancreatitis, e.g. abdominal pain that may radiate to the back or shoulder, nausea and vomiting. • instruct patients to stop taking eluxadoline and seek immediate medical attention if these symptoms develop. • report all suspected adverse drug reactions to Black Triangle drugs such as Truberzi® to the Yellow Card Scheme				
Reason why eluxadoline has been chosen in preference to drugs without Formulary restrictions:	**Specialists please type text below and check boxes**: Eluxadoline is recommended as an option for treating irritable bowel syndrome with diarrhoea in adults, only if:				
	• the condition has not responded to other pharmacological treatments				Please tick ☐
		Name of the agent(s)	**Dose**	**Duration of use**	**Reason for discontinuation**
	Antimotility agents				
	Antispasmodics				
	Tricyclic antidepressants				
	OR				
	• pharmacological treatments are contraindicated or not tolerated				Please tick ☐
	AND				
	It is started in secondary care.	**YES**	Dose	Duration of use	
Pre-treatment test results	Specialists please complete the information in table below: Liver function test Somnolence and sedation Alcohol history				
Contraindication for using eluxadoline. (drug safety alert)	Alcoholism, alcohol abuse, alcohol addiction or chronic or acute excessive alcohol use			☐ YES	☐ NO
	Known or suspected biliary duct obstruction or sphincter of Oddi disease or dysfunction			☐ YES	☐ NO
	Patients without a gallbladder (e.g. due to cholecystectomy or agenesis)			☐ YES	☐ NO
	Patients on treatment with potent inhibitors of OATP1B1 (e.g. ciclosporin)			☐ YES	☐ NO
	A history of pancreatitis; or known or suspected structural diseases of the pancreas, including pancreatic duct obstruction			☐ YES	☐ NO
	Hepatic impairment (Child-Pugh Class A-C)			☐ YES	☐ NO
	A history of chronic or severe constipation or sequelae from constipation, or known or suspected mechanical gastrointestinal obstruction			☐ YES	☐ NO

Guidance on initiation (to be completed by the specialist)

Initiation dose:	The recommended dose is 200 mg daily (one 100 mg tablet, twice daily). For patients who are unable to tolerate the 200 mg daily dose (one 100 mg tablet, twice daily), the dose can be lowered to 150 mg daily (one 75 mg tablet twice daily).
Specialist recommendations	Specialist to complete
Monitoring:	Liver function test Somnolence and sedation Alcohol consumption

Suggested Criteria for Continuation or Discontinuation (to be completed by the specialist)

Assessment of Efficacy	
Frequency	Initial review to be complete by specialist – if there is inadequate relief of the symptoms of irritable bowel syndrome with diarrhoea at 4 weeks - Stop eluxadoline
Location	Initial review is by specialist Following reviews – outpatient/GP practice
Method	
Continuation Criteria	Consider transfer to primary care if adequate relief of the symptoms of irritable bowel syndrome with diarrhoea after 4 weeks.
Review	Stop eluxadoline at 4 weeks if there is inadequate relief of the symptoms of irritable bowel syndrome with diarrhoea.
Discontinuation Criteria	There is a potential for increased risk of constipation when taking eluxadoline. If patients develop severe constipation for a duration of more than 4 days, they should be instructed to stop the treatment and seek medical attention Liver function - hepatic impairment (Child-Pugh Class A-C)
	MHRA Drug Safety alert (Dec 2017) Advice for healthcare professionals: • eluxadoline (Truberzi®▼), licenced for irritable bowel syndrome with diarrhoea, should be initiated and supervised by a specialist physician experienced in diagnosis and management of gastrointestinal disorders • **do not** use in patients without a gallbladder or in patients with known or suspected biliary tree or pancreatic duct obstruction (eg, gallstones, tumour, periampullary duodenal diverticulum) or sphincter of Oddi disease or dysfunction • tell patients to avoid drinking alcohol during treatment with eluxadoline • inform patients about symptoms suggestive of pancreatitis—e.g. abdominal pain that may radiate to the back or shoulder, nausea, and vomiting • instruct patients to stop taking eluxadoline and seek immediate medical attention if these symptoms develop • report all suspected adverse drug reactions to Black Triangle drugs such as Truberzi to the Yellow Card Scheme
Follow up action	Specialist to complete If patients develop severe constipation for a duration of more than 4 days – stop treatment and discuss with specialist team. Liver function test - Hepatic impairment (Child-Pugh Class A-C) - withhold until discussed with specialist team. Somnolence and sedation - caution should be exercised.
Additional Information	Eluxadoline ▼is a black triangle drug. All suspected adverse effects should be reported to the MHRA www.yellowcard.gov.uk
Shared Care Read Code	In the patients notes, using the appropriate Read Code listed below, denote that the patient is receiving treatment under a shared care agreement/RICaD

GP Prescribing System	Read Code	Description
EMIS and Vision	8BM5.00	Shared care prescribing
SystmOne	XaB58	Shared care

References	NICE TA 471: Eluxadoline for treating irritable bowel syndrome with diarrhoea Truberzi®▼ SPC MHRA Drug Safety Update Dec 2017: Eluxadoline (Truberzi®▼): risk of pancreatitis.

Please note the information included in this document is correct at the time of writing.
The manufacturer's Summary of Product Characteristics (SPC) and the most current edition of the British National Formulary should be consulted for up to date and more detailed prescribing information.