Rationale for Initiation, Continuation and Discontinuation (RICaD)

Roflumilast▼

For treating chronic obstructive pulmonary disease

This document supports the use and transfer of an agent which is classified as **AMBER**.
It is intended for completion by specialists 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 roflumilast under the restrictions listed below**	
DOB				**Signature**	
Patient address				**Date**	
				Contact details	

Rationale for Choice

Relevant Diagnosis:	Chronic obstructive pulmonary disease (18 years and over)		
Agreed Indication(s) for inclusion in the BSSE APC Formulary:	To be used in line with NICE TA461 - Roflumilast for treating chronic obstructive pulmonary disease Roflumilast, as an add-on to bronchodilator therapy, is recommended as an option for treating severe chronic obstructive pulmonary disease in adults with chronic bronchitis, only if: • the disease is severe, defined as a forced expiratory volume in 1 second (FEV_1) after a bronchodilator of less than 50% of predicted normal ☐ **and** • the person has had 2 or more exacerbations in the previous 12 months despite triple inhaled therapy with a long-acting muscarinic antagonist, a long-acting beta-2 agonist and an inhaled corticosteroid. ☐ Treatment with roflumilast should be started by a specialist in respiratory medicine.		
Reason why Roflumilast has been chosen in preference to drugs without Formulary restrictions:	*Specialist to complete*		
	Class	Name of agent	Dose
	Long-acting muscarinic antagonist		
	Long-acting beta-2 agonist		
	Inhaled corticosteroid		
Pre-treatment test results	Liver function test (to be used as a baseline reference for ongoing monitoring, and detection of abnormal LFTs) Body weight (baseline and body weight of underweight patients should be checked at each visit)		

Guidance on initiation

Initiation dose:	The recommended dose is 500 micrograms (one tablet) roflumilast once daily.
Additional info:	• All patients should be informed about the risks of roflumilast and the precautions for safe use and should be given a patient card before starting roflumilast. • Psychiatric disorders: roflumilast is not recommended in patients with a history of depression associated with suicidal ideation or behaviour. Patients and caregivers should be instructed to notify the prescriber of any changes in behaviour or mood and of any suicidal ideation. • Treatment with roflumilast should not be initiated or existing treatment with roflumilast should be stopped in patients with severe immunological diseases (e.g. HIV infection, multiple sclerosis, lupus erythematosus, progressive multifocal leukoencephalopathy), severe acute infectious diseases, cancers (except basal cell carcinoma), or patients being treated with immunosuppressive medicinal products (i.e.: methotrexate, azathioprine, infliximab, etanercept, or oral corticosteroids to be taken long-term; except short-term systemic corticosteroids). • Patients with congestive heart failure (NYHA grades 3 and 4) have not been studied and therefore treatment of these patients is not recommended. • Women of childbearing age should be advised to use an effective method of contraception during treatment. Roflumilast is not recommended in women of childbearing potential not using contraception.
Monitoring:	Liver function test Body weight (baseline and body weight of underweight patients should be checked at each visit)

Suggested Criteria for Continuation or Discontinuation

Assessment of Efficacy	
Frequency	Once stabilised, review 3 monthly. Rationale: side effects are common and need regular monitoring.
Location	Outpatients clinic/GP practice (delete as applicable)
Monitoring (tests required)	Body weight (baseline and body weight of underweight patients should be checked at each visit)
Continuation Criteria	Roflumilast may need to be taken for several weeks to achieve its effect. Efficacy is determined by decrease in exacerbations of COPD. Roflumilast has been studied in clinical trials for up to one year. Studies of exacerbation rate require a year to run in part because they are seasonal hence any efficacy review could take up to a year. Roflumilast may be continued after one year if good response is achieved.
Discontinuation Criteria	• Unexplained and clinically concerning weight decrease, the intake of roflumilast should be stopped and body weight should be further followed-up. • If patient suffered from new or worsening psychiatric symptoms, or suicidal ideation or suicidal attempt is identified, it is recommended to discontinue treatment with roflumilast. • If patient develops moderate- severe liver impairment, discontinue treatment with roflumilast. • Roflumilast treatment should be reassessed in case of persistent intolerability (adverse reactions like diarrhoea, nausea, abdominal pain and headache), and a high level of side effect would warrant cessation.
Follow up action	*Specialist to complete*
Shared Care Read Code	In the patient's 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 TA461 - Roflumilast for treating chronic obstructive pulmonary disease SmPC Daxas®▼ (roflumilast)
Additional Information	Roflumilast ▼is a black triangle drug. All suspected adverse effects should be reported to the MHRA www.yellowcard.gov.uk

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.