Rationale for Initiation, Continuation and Discontinuation (RICaD)

Ciclesonide

Severe, difficult to treat asthma

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 ciclesonide under the restrictions listed below**	
DOB				**Signature**	
Patient address				**Date**	
				Contact details	

Rationale for Choice

Relevant Diagnosis:	Severe difficult to treat asthma
Agreed Indication(s) for inclusion in the BSSE APC Formulary:	1. Severe, difficult to treat asthma in patients with high levels of airway inflammation despite high dose inhaled corticosteroid therapy. 2. Patients with asthma who require ICS therapy and are intolerant of other ICS preparations or have evidence of systemic side effects (accelerated osteoporosis, adrenal suppression) For initiation by a Respiratory specialist and maintenance by primary care. ***Note: often used in addition to other inhalers including those containing corticosteroids***
Reason why Ciclesonide has been chosen in preference to drugs without Formulary restrictions:	As ciclesonide is delivered as a pro drug and converted to an active metabolite in the lung, there is a reduced likelihood of local upper airway steroid deposition or systemic absorption of steroid. In severe, difficult to treat asthma there are high levels of inflammation in the lungs therefore patients require more inhaled corticosteroid (ICS) to bring their asthma under control. This can be achieved by adding stand alone inhaled steroid on top of their regular combination ICS/LABA inhaler. In this instance, adding ciclesonide is an option. It has a lower systemic side effect profile than oral steroids such as prednisolone. Additionally, the benefits of inhaled ciclesonide should minimise the need for oral steroids.
Pre-treatment test results	Patients should have evidence of eosinophilic airway inflammation (peripheral blood eosinophils 0.4 or higher or FeNO > 25ppb) despite treatment with ICS/LABA combination inhaler

Guidance on initiation

Initiation dose:	80-160micrograms OD preferably in the morning
Additional info:	In patients with severe asthma and while reducing or discontinuing oral corticosteroids, a higher dose of up to 640microg/day (given as 320microg twice daily) may be used. Patients should be given a dose of inhaled ICS which is appropriate to the severity of their disease. Once control is achieved, the dose of ciclesonide should be individualised and titrated to the minimum dose needed to maintain good asthma control. Dose reduction to 80micrograms OD may be an effective maintenance dose in some patients.

Monitoring:	No monitoring is required Efficacy and ongoing requirement should be assessed by clinical response and change in markers of eosinophilic inflammation

Suggested Criteria for Continuation or Discontinuation

Assessment of Efficacy	
Frequency	Initial assessment of efficacy after 6-12 months of treatment
Location	Outpatients clinic/GP practice
Method (what tests are required)	Clinician review (focus on symptom control and exacerbations) FeNO when available Peripheral Blood eosinophils
Continuation Criteria	Evidence of benefit
Discontinuation Criteria	No change in number of exacerbations after 12 months treatment
Follow up action	Consider alternative treatment options (see asthma treatment guidelines) Continue to monitor for evidence of inflammation
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	Alvesco® SmPC

Appendix: Important information from the Summary of Product Characteristics (SPC)

Agreed Indication(s) for inclusion in the BSSE APC Formulary:	Severe, difficult to treat asthma.
Special precautions	**Contraindications** - Hypersensitivity to ciclesonide or excipients **Cautions** - Active or quiescent pulmonary tuberculosis, fungal, viral or bacterial infections, and only if these patients are adequately treated. - Acute episodes of asthma where intensive measures are required. - The transfer of oral steroid-dependent patients to inhaled ciclesonide, and their subsequent management, needs special care as recovery from impaired adrenocortical function, caused by prolonged systemic steroid therapy, may take a considerable time.
Significant Drug Interaction	- *In vitro* data indicate that CYP3A4 is the major enzyme involved in the metabolism of the active metabolite of ciclesonide. - Therefore the concomitant administration of potent inhibitors of CYP 3A4 (e.g. ketoconazole,

(please see SPC for more detail)	itraconazole and ritonavir or nelfinavir) should be avoided unless the benefit outweighs the increased risk of systemic side effects of corticosteroids.
Additional info:	- Possible systemic effects include adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract and glaucoma, and more rarely, a range of psychological or behavioral effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). It is therefore important that the dose of inhaled corticosteroid is titrated to the lowest dose at which effective control of asthma is maintained. - Recommended that the height of children and adolescents receiving prolonged treatment with inhaled corticosteroids is regularly monitored.

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.