Rationale for Initiation, Continuation and Discontinuation (RICaD)

Aliskiren

For the treatment of essential hypertension

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**	
PID		**GP address**		**I confirm that this patient is eligible to receive aliskiren under the restrictions listed below**	
DOB				**Signature**	
Patient address				**Date**	
				Contact details	

Rationale for Choice

Relevant Diagnosis:	Hypertension ☐
Agreed Indication(s) for inclusion in the BSSE APC Formulary:	At step 4 of the ACD algorithm, as a further option (alongside alpha blockers, beta blocker and loop diuretics) for treatment of hypertension in patients with BP >140/90mmHg despite previous treatment with 3 or more antihypertensive agents. In patients with difficult and multiple antihypertensive drug intolerances, aliskiren may be used alone or in fewer combinations when the previous treatment listed has failed.
Reason why aliskiren has been chosen in preference to drugs without Formulary restrictions:	Resistant hypertension despite multiple treatments (as listed below) ☐ Intolerance to treatments. ☐ 1. 2. 3. 4.
Special precautions	**Contraindications** • Hypersensitivity to the active substance or to any of the excipients listed • History of angioedema with aliskiren. • Hereditary or idiopathic angioedema. • Second and third trimesters of pregnancy. • The concomitant use of aliskiren with ciclosporin and itraconazole, two highly potent P-gp inhibitors, and other potent P-gp inhibitors (e.g. quinidine), is contraindicated • The concomitant use of aliskiren with an ACEI or an ARB is contraindicated in patients with diabetes mellitus or renal impairment (eGFR < 60 ml/min/1.73 m^2). • Children from birth to less than 2 years **Caution** (As per BNF online May 15- for more information please see SmPC) • taking concomitant diuretics • on a low-sodium diet, or who are dehydrated (first doses may cause hypotension—initiate with care) • renal artery stenosis - monitor renal function • patients at risk of renal impairment- monitor renal function • diabetes mellitus- monitor glucose tolerance • moderate to severe heart failure • In the event of severe and persistent diarrhoea, aliskiren therapy should be stopped

Drug Interaction (significant interaction as outlined in BNF, please see BNF and SPC for more detail)	**Aliskiren** has the following interaction information:

ACE Inhibitors	increased risk of hyperkalaemia, hypotension, and impaired renal function when aliskiren given with ACE inhibitors —avoid concomitant use
Angiotensin-II Receptor Antagonists	increased risk of hyperkalaemia, hypotension, and impaired renal function when aliskiren given with angiotensin-II receptor antagonists — avoid concomitant use
Ciclosporin	plasma concentration of aliskiren increased by ciclosporin —avoid concomitant use
Grapefruit Juice	plasma concentration of aliskiren reduced by grapefruit juice —avoid concomitant use
Itraconazole	plasma concentration of aliskiren increased by itraconazole —avoid concomitant use

Pre-treatment test results

Date of test	
Sodium	
Potassium	
Creatinine	
eGFR	

The patient has been informed of the need for frequent blood pressure monitoring and blood test (U&E) whilst taking aliskiren in order to assess its efficacy.
Please cross box ☐
The patient has been given a shared care card.
Please cross box ☐

Guidance on initiation

Initiation dose:	The recommended dose of aliskiren is 150 mg once daily. In patients whose blood pressure is not adequately controlled, the dose may be increased to 300 mg once daily
Additional info:	Aliskiren should be taken with a light meal once a day, preferably at the same time each day. Concomitant intake with fruit juice and/or drinks containing plant extracts (including herbal teas) should be avoided The effect of aliskiren on warfarin pharmacokinetics has not been evaluated. SmPC can be accessed at http://emc.medicines.org.uk

Monitoring:	Patient to have blood pressure monitored in primary care – e.g. weekly at 2, 3 and 4 weeks by a practice nurse to allow average BP on therapy to be determined.
	
	Patient to have U&E checked in primary care at 5 to 7 days after starting aliskiren and after each increase in dose.
	
	If deranged, discontinue and contact specialist for advice
	• Renal function should be assessed from glomerular filtration rates (eGFR).
	• Use caution if eGFR < 60ml/min/1.73m^2
	• Aliskiren should not be used if eGFR is <30 ml/min/1.73m^2.
	• Aliskiren treatment requires review if
	  ○ Serum K is 5.5 mmol/l or more
	• Aliskiren treatment requires suspension if:
	  ○ K+ > 6.0 mmol/L
	  ○ eGFR falls by >20%
	  ○ **Specialist advice should be sought**
	
	In all patients where aliskiren treatment is continued or initiated, eGFR and glucose tolerance should be monitored at appropriate intervals

Suggested Criteria for Continuation or Discontinuation

<table>
<tr><th colspan="2">Assessment of Efficacy</th></tr>
<tr><td>Frequency:</td><td>After at least 3-4 weeks of taking aliskiren (and after 3 BP readings)</td></tr>
<tr><td>Location:</td><td>GP practice</td></tr>
<tr><td>Method:</td><td>Patient to have blood pressure measured at practice on three separate dates by practice nurse – after taking the drug for at least 3-4 weeks.
Please write these readings down (on shared care card if available) for the patient to bring to secondary care.
Those blood pressures to be averaged and compared to last recorded pre-aliskiren blood pressure (“baseline” BP)</td></tr>
<tr><td>Continuation Criteria:</td><td>A fall in average systolic BP of 5 mm Hg or more.</td></tr>
<tr><td>Review and up-titration :</td><td>Confirm compliance.
If fall in average systolic BP is less than 5 mmHg, see discontinuation criteria, below, and consider stopping.
If further BP lowering required, up-titrate to aliskiren 300 mg od
Monitor U & Es after 5-7 days of start and each dose increase.
Reassess efficacy as above at least 2 weeks after dose increase.</td></tr>
<tr><td>Discontinuation criteria:</td><td>No decrease in average systolic BP on aliskiren 150 mg od (in a compliant patient).
A fall in average systolic BP of less than 5 mm Hg on 300 mg od (in a compliant patient).
In either case, stop drug and confirm with patient that they have a follow-up with secondary care.</td></tr>
<tr><td>Follow up action</td><td>The patient will be reviewed in secondary care within 3 months of starting aliskiren.</td></tr>
<tr><td>Shared Care read code:</td><td>In the patients notes, using the appropriate Read Code listed below, denote that the patient is receiving treatment under a shared care agreement/RICaD
<table>
<tr><th>GP Prescribing System</th><th>Read Code</th><th>Description</th></tr>
<tr><td>EMIS and Vision</td><td>8BM5.00</td><td>Shared care prescribing</td></tr>
<tr><td>SystmOne</td><td>XaB58</td><td>Shared care</td></tr>
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