FULL SHARED CARE AGREEMENT FOR

Aliskiren (Rasilez)

in the treatment of

Hypertension

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Additional medicines information is available from:

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**Full Shared Care Policy for the prescribing of aliskiren in the treatment of hypertension**

**Introduction and purpose**

This shared care agreement has been produced following classification of aliskiren in the Leicestershire drug traffic light scheme. See website at [www.lmsg.nhs.uk](http://www.lmsg.nhs.uk)

Shared care has been defined as the mechanism of sharing patient care between primary and secondary care providers. This document sets out these responsibilities from initial diagnosis to on going support.

**Disease Background**

Hypertension is a common condition with increasing prevalence in older populations. Most patients (90%) have essential hypertension and the majority have well-controlled BP taking 2-3 anti-hypertensive drugs. A small percentage of patients have resistant hypertension (with no evidence of an underlying cause or white-coat effect etc) and these patients can often require 4 drugs or more for good BP control. In addition, there are a small number of patients who do not tolerate anti-hypertensive therapy due to side-effects to multiple drugs.

**Drug covered by the agreement**

Aliskiren is a novel oral direct renin inhibitor and therefore produces its anti-hypertensive effect via inhibition of the renin-angiotensin-aldosterone system. [Reduction in the production of angiotensin II and aldosterone leads to vasodilatation and reduced salt and water retention].

In pre-marketing trials, aliskiren was identified as an effective anti-hypertensive as a sole agent and in combination with an ACE inhibitor (ACEi - ramipril), Angiotensin Receptor Blocker (ARB - valsartan), thiazide diuretic (hydrochlorothiazide) or CCB (amlodipine). Adverse drug reactions (ADRs) were rare – diarrhoea was reported more frequently at 300 mg doses (2.3% v. 1.3%) compared to placebo, but this ADR is dose dependent – 6.9% of 600 mg dose (unlicensed) patient reported diarrhoea. Like ACEi and ARB drugs, aliskiren can increase serum potassium, but this is rare.

Aliskiren is an option for the treatment of hypertensive patients with either multiple drug intolerances or resistant hypertension (on 3+ drugs). It is a good alternative to β-blockers, α-blockers, or spironolactone and therefore can be considered as a 4th line agent. Within UHL aliskiren is supported only for initiation in the hypertension clinic and specialist renal and diabetes clinics.

Currently, there is no evidence to support the use aliskiren in pregnancy or severe renal failure (GFR<30)

**NB: The combination of aliskiren (Rasilez) with angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs) has been associated with serious adverse cardiovascular and renal outcomes in a recent large clinical trial (ALTITUDE). This combination is now contraindicated in: diabetic patients (type I or type II); and non-diabetic patients with an estimated glomerular filtration rate (eGFR) <60 mL/min per 1.73 m²**

In all other patient groups, aliskiren in combination with an ACE inhibitor or an ARB is not recommended.
Any use of aliskiren (either as monotherapy or in combination with other medicines) is no longer recommended in any patient with severe renal impairment: eGFR <30 mL/min per 1.73 m²

Secondary Care Clinician Responsibilities

- Diagnosis of hypertension and ensuring other treatment options have been fully explored.
- Identification of those patients who would specifically benefit from aliskiren mindful of the alternatives of other 4th line drugs for hypertension.
- Ensuring that recent U+Es are available before prescribing.
- Initiation of aliskiren at 150 mg daily
- Arranging for U+Es to be monitored 7-10 days after initiation and informing the GP and patient. If appropriate, a blood form can be given to the patient to take away to undertake the test in primary care if this is convenient. Results will be interpreted and appropriate action taken by the secondary care physician.
- Advising the patient and GP of potential adverse drug effects and action to take if they occur.
- Liaison with the general practitioner (GP) to share the patient’s care when a stable dose has been achieved and proven benefit has been established using the Shared Care Agreement Form. Shared care should not be assumed until a written agreement has been received from the GP.
- Advising the GP that up-titration of the dose to 300 mg can be considered one month after initiation if further BP lowering is required and the patient has tolerated the drug.
- The patient should be reviewed in secondary care within two months of the initiation of aliskiren. Up-titration of the dose should be considered if this has not already occurred.
- Advising the GP of the cautions of co-prescribing potential renal toxic and potassium-sparing drugs (similar to advice given regarding ACEi and ARB drugs).
- Responding to issues raised by GP after care of patient has been transferred

GP Responsibilities

- Confirm or decline request to share patient’s care as soon as possible, using the shared care agreement form.
- Monitoring the patient’s overall health and well being and observing patient for evidence of ADRs/abnormalities and raising with secondary care clinician if necessary.
- Taking over prescribing of aliskiren if the patient is stable on either dose of aliskiren.
- Undertaking annual monitoring of BP and U+Es.
- Ensuring advice is sought from the secondary care clinician if there is any significant change in the patient’s physical health status

Contact for support and advice

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**Supporting Information**

Summary of Product Characteristics (SPC) Razilez® aliskiren (Generic); Novartis

Reference to shared care agreement form added June 2011