South East London Area Prescribing Committee
Position Statement

Reference:	**PS-025**
Intervention:	**Aliskiren for hypertension**
Date of Decision:	**June 2020**
Date of Issue:	**July 2020**
Recommendation:	**RED – Suitable for prescribing and supply by hospital only** South East London CCG does not support the routine prescribing of aliskiren. 1) Aliskiren should only be initiated under hospital or specialist supervision and no new patients should be started on aliskiren for hypertension 2) Review patients prescribed aliskiren and switch to an alternative antihypertensive agent in line with NICE guidance NG136 (unless they are under specialist management). Check Blood pressure, lifestyle review and CV risk score, and deprescribe and/or switch to an alternative antihypertension. 3) Review of patients admitted to hospital taking aliskiren.
Further Information:	1. Aliskiren is included in updated guidance from NHS England on low priority products as a medicine less suitable for routine prescribing. 2. NICE do not recommend the use of aliskiren due to insufficient evidence of its effectiveness in resistant hypertension. Whilst it has shown comparable efficacy to other antihypertensive agents in terms of blood pressure reduction, its effects on mortality and long-term morbidity are currently unknown. In updated NICE guidance 2019, step 4 treatment now consists of low dose spironolactone and/or beta/alpha- blockers. 3. The Scottish Medicine Consortium does not recommend aliskiren as insufficient clinical and cost-effective information for mortality and long-term morbidity. 4. In 2014, the MHRA recommended caution with aliskiren following the ALTITUDE study (see reference below) for the following patients: § Prescribers should review the treatment of all patients taking aliskiren in combination with an ACE inhibitor or an ARB. § In patients who are taking an ACE inhibitor or an ARB, healthcare professionals should stop aliskiren and not initiate new treatment in: a) diabetic patients; and b) non-diabetic patients with an eGFR <60 mL/min per 1.73 m2 § Aliskiren in combination with ACE inhibitors or ARBs is not recommended in any other patients. The benefits versus risks of continuing aliskiren treatment should be considered carefully. § If aliskiren is discontinued then alternative antihypertensive agents should be used as necessary § Use of aliskiren (either as monotherapy or in combination with other medicines) is no longer recommended in patients with severe renal impairment—i.e., eGFR <30mL/min per 1.73 m2 § In all patients where aliskiren treatment is continued or initiated, eGFR and glucose tolerance should be monitored at appropriate intervals. 5. There have also been reports of angioedema and acute renal impairment in patients taking aliskiren through the yellow card reporting system: 20 reports of renal disorders with 1 fatal case, plus 12 cases of angioedema to Sept 2019. (www.info.mhra.gov.uk/drug-analysis-profiles)

Cost Impact for agreed patient group	There is low spend on aliskiren in primary care across SEL (<£10K).
Usage Monitoring & Impact Assessment	**Acute Trusts** · Monitor use and audit upon request to ensure use is in line with this position statement.
	SEL CCG Borough Teams: · Ongoing review of prescribing data (EPACT2) · Monitor exception reports from GPs if inappropriate requests to prescribe are made to primary care.
Evidence reviewed:	1. NICE guidance: Hypertension in adults, diagnosis and management NG136, August 2019; https://www.nice.org.uk/guidance/NG136 2. Scottish Medicine Consortium, Jan 2010: aliskiren is not recommended for use in NHS Scotland for the treatment of essential hypertension. https://www.scottishmedicines.org.uk/medicines-advice/aliskiren-rasilez-resubmission-46208/ 3. H.Parving et al; Cardiorenal End Points in a Trial of Aliskiren for Type 2 Diabetes; NEJM 2012; 367:2204-2213; https://www.nejm.org/doi/pdf/10.1056/NEJMoa1208799?articleTools=true 4. MHRA 2014; https://www.gov.uk/drug-safety-update/aliskiren-rasilez-risk-of-cardiovascular-and-renal-adverse-reactions 5. Interactive drug analysis profile for aliskiren/rasilez: https://info.mhra.gov.uk/drug-analysis-profiles/dap.html?drug=./UK_EXTERNAL/NONCOMBINED/UK_NON_000330303774.zip&agency=MHRA

NOTES:

a) Area Prescribing Committee recommendations, position statements and minutes are available publicly via the APC website.

b) This Area Prescribing Committee position statement has been made on the cost effectiveness, patient outcome and safety data available at the time. The position statement will be subject to review if new data becomes available, costs are higher than expected or new NICE guidelines or technology appraisals are issued

c) Not to be used for commercial or marketing purposes. Strictly for use within the NHS