Specialist Initiated Drugs
Prescribing Information Sheet June 2016

Sacubitril valsartan for the treatment of symptomatic heart failure

NICE recommendation

NICE TA 233 states that sacubitril valsartan is recommended for the treatment of symptomatic heart failure if the patient meets the following criteria for use:

- Chronic stable heart failure – New York Heart Association (NYHA) class II-IV
- Left ventricular systolic dysfunction with ejection fraction <35%
- Stable on an Angiotensin-Converting Enzyme (ACE) inhibitors or Angiotensin II Receptor Blocker (ARB)

Treatment with sacubitril valsartan should be started by a heart failure specialist with access to a multidisciplinary heart failure team. Dose titration and monitoring should be performed by the most appropriate team member as defined in NICE's guideline on chronic heart failure in adults.

It has been agreed in East Kent that before treatment with sacubitril valsartan patients should be tolerating a therapeutic dose of ACE inhibitor or ARB as specified below:

ACE inhibitor / ARB	**East Kent minimum dose Criteria**
Enalapril	10mg bd
Lisinopril	10mg od
Perindopril	2mg od
Ramipril	2.5mg bd or 5mg od
Losartan	50mg od
Candesartan	16mg od
Valsartan	160mg od
Irbesartan	150mg od

The target dose of sacubitril valsartan contains 103mg valsartan which is equivalent to 160mg of valsartan montherapy. Trial data from Paradigm showed superior efficacy to enalapril 10mg bd.

Approved by: East Kent Prescribing Group *(Representing Ashford CCG, Canterbury and Coastal CCG, South Kent Coast CCG and Thanet CCG)*
Date: June 2016
Address: c/o *Canterbury and Coastal CCG, Ground Floor, Council Offices, Military Road, Canterbury, Kent,CT1 1YW*
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Formulary Status

Initiation and Titration

1. Patients will only be recommended for initiation on this drug by a cardiologist, in liaison with the KCHFT cardiac nursing team**. All patients must be referred to the cardiac nursing team for initiation to take place.**
2. Patients can only be initiated on this drug when they are clinically stable. It is therefore anticipated that patients will be initiated in primary care. GPs will be asked to prescribe the initial prescription supported by the KCHFT cardiac nurse team. This will ensure that the patient's repeat medication is updated correctly at initiation to avoid concurrent use with an ACE inhibitor or ARB.
3. The KCHFT cardiac team will take responsibility for communicating with the patient's GP using a standard proforma and supporting the GP with any clinical issues.

The KCHFT cardiac team will take responsibility for:

- **Counselling the patient and ensuring that they understand that they should no longer take their current prescription for an ACE inhibitor, ARB or aliskiren.**
- Assessing the patient's ability to concord with treatment.
- **Ensuring a 48 hour washout period for patients taking ACE inhibitors.**
- Requesting the GP to prescribe the initial and ongoing prescriptions for sacubitril valsartan and **to remove any ACE inhibitors, ARBs or aliskiren from the patient's medication list.**
- Monitoring the patient regularly for the first 3 months of treatment, including U&Es and renal function 7- 10days after intiation and titrating the dose up as clinically appropriate.
- Liaising with the cardiologist regarding any clinical concerns.
- Informing the GP of any clinical concerns, requirements to change the dose of sacubitril valsartan or to stop treatment.
- Reporting adverse reactions via yellow card system before GP takes over prescribing

The GP will be asked to take responsibility for:

- **Removing the ACE inhibitor, ARB or aliskiren from the patient's medication list.**
- Prescribing the sacubitril valsartan in accordance with the cardiac nurse's written request.
- Actioning any changes required to the dose or treatment in accordance with the cardiac nurse's written request.
- Assuming ongoing responsibility for monitoring once the patient has been stabilised on a maintenance dose – blood pressure, renal function and potassium need to be monitored at least 6 monthly.
- Reporting adverse reactions via yellow card system

Clinical Information

For full prescribing information see https://www.medicines.org.uk/emc/medicine/31244

Sacubitril valsartan is an angiotensin receptor neprilysin inhibitor, including both a neprilysin inhibitor (sacubitril) and an angiotensin II receptor blocker (ARB; valsartan). Both lower blood pressure.

Sacubitril valsartan is administered orally. The recommended starting dose is one 49/51 mg tablet, twice daily (each tablet contains 48.6 mg sacubitril and 51.4 mg valsartan). The dose should be doubled at 2 to 4 weeks to the target dose of one 97/103 mg tablet (97.2 mg sacubitril and 102.8 mg valsartan) twice daily, as tolerated by the patient.

Patients must not take other drugs acting on the angiotensin system concurrently eg. ACE inhibitors, ARBs or aliskiren. Patients taking ACE inhibitors must have a 48 hour washout period before they commence sacubitril valsartan because of the increased risk of angioedema. This is also required if ACE inhibitor treatment is recommenced in place of sacubitril valsartan.

The most commonly reported adverse reactions during treatment with sacubitril valsartan are hypotension, hyperkalaemia and renal impairment. Reported adverse events are generally in line with that reported for other medicinal products acting on the renin-angiotensin-aldosterone system.

Cardiac Nurse Team Locality Offices

Canterbury	0300 123 1412	Dover/Deal	01304 865457
Shepway	01303 858931	Thanet	0300 123 3027
Ashford	0300 7900 272		

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