Berkshire West Integrated Care System
Representing
Berkshire West Clinical Commisioning Group
Royal Berkshire NHS Foundation Trust
Berkshire Healthcare NHS Foundation Trust
Berkshire West Primary Care Alliance

Prescribing Guidelines

Prescribing arrangement for the management of patients transferring from ***Secondary Care to Primary Care***

Sacubitril valsartan for the treatment of symptomatic heart failure

APC PG 020

For the latest information on interactions and adverse effects, always consult the latest version of the Summary of Product Characteristics (SPC), which can be found at: http://www.medicines.org.uk/

Approval and Authorisation

Approved by	Job Title	Date
BW Area Prescribing Committee	A Penn, APC Chair	March 2017
RBH Drugs and Therapeutics Committee	S Hussain, DTC Chair	June 2017

Change History

Version	Date	Author	Reason
v.1.0	1st March 2017	A Scott	New Document
v.1.1	17th March 2017	A Scott	Changes requested by APC. Signed off at GP MOC 15.3.17

This prescribing guideline remains open to review considering any new evidence.

This guideline should only be viewed online and will no longer be valid if printed off or saved locally

Author	A Scott	Date of production:	March 2017
Job Title	Lead Interface Pharmacist	Review Date	March 2020
Protocol Lead	L Tilling, Consultant; Heart Failure Specialist	Version	v.1.1

PRESCRIBING GUIDANCE

Sacubitril valsartan for the treatment of symptomatic heart failure

Introduction

This guidance has been prepared to support healthcare professionals in the implementation of shared care management of patients who have been prescribed sacubitril valsartan by the heart failure team and in accordance with NICE TA 388 available at https://www.nice.org.uk/guidance/ta388

Sacubitril valsartan (Entresto, Novartis) has a UK marketing authorisation for 'the treatment of symptomatic chronic heart failure with reduced ejection fraction'. Sacubitril valsartan is an angiotensin receptor neprilysin inhibitor, including both a neprilysin inhibitor (sacubitril) and an angiotensin II receptor blocker (ARB; valsartan). Both sacubitril and valsartan lower blood pressure

Dose

Sacubitril valsartan is administered orally. The recommended starting dose is one 49/51 mg tablet, twice daily (each tablet contains 48.6mg sacubitril and 51.4mg 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.

Cautions

- Hypotension
- Worsening renal function

- Hyperkalaemia
- Angioedema
- Patients with renal artery stenosis
- Patients with hepatic impairment

Contraindications
• Hypersensitivity to the active substances or to any of the excipients
• Concomitant use with ACE inhibitors. Sacubitril valsartan must not be administered until 36 hours after discontinuing ACE inhibitor therapy.
• Known history of angioedema related to previous ACE inhibitor or ARB therapy
• Hereditary or idiopathic angioedema
• Concomitant use with aliskiren-containing medicinal products in patients with diabetes mellitus or in patients with renal impairment (eGFR <60 ml/min/1.73 m^2)
• Severe hepatic impairment, biliary cirrhosis and cholestasis.
• Second and third trimester of pregnancy.

Side effects
- Anaemia
- Dizziness
- Headache
- Syncope
- Cough
- Diarrhoea
- Nausea
- Gastritis

Interactions
The following drugs should not be initiated by a GP unless discussed with a consultant cardiologist or a member of the heart failure team

Interacting Drug	Effect
ACE Inhibitors	Increased risk of angioedema. A washout period of 36 hours must be observed before stopping one treatment and initiating another
Aliskiren	higher frequency of adverse events such as hypotension, hyperkalaemia and decreased renal function (including acute renal failure)
PDE5 inhibitors e.g. sildenafil	Greater blood pressure reduction
Furosemide	Decrease in AUC of furosemide
Lithium	Reversible increase in lithium concentrations
Drugs which increase potassium such as spironolactone, potassium sparing diuretics	Hyperkalaemia

Criteria for Use

RESPONSIBILITIES and ROLES

Specialist responsibilities
1 Carry out baseline and subsequent monitoring.
2 Initiate treatment and titrate to a stable level.
3 Send a letter to the GP requesting shared care for the patient after 3 months.
4 Routine clinic follow-up on a regular basis.
5 Send a letter to the GP after each clinic attendance ensuring current dose, most recent blood results and frequency of monitoring are stated.
6 Evaluation of any reported adverse effects by GP or patient.
7 Advise GP on review, duration or discontinuation of treatment where necessary.
8 Inform GP of patients who do not attend clinic appointments.
9 Ensure that backup advice is available at all times

Monitoring requirements and actions (to be undertaken by the hospital)	
• Pre-treatment FBC, U&Es, LFT's, CRP, cholesterol, blood glucose, blood pressure • Subsequent Monitoring • **U&E's, LFT's & FBC** – Before initiating treatment then annually thereafter	
Potassium levels > 5.4mmol/l	If patients experience clinically significant hyperkalaemia adjustment of concomitant medicinal products, or temporary down–titration or discontinuation is recommended. If serum potassium level is >5.4 mmol/l discontinuation should be considered
Creatinine above 130 mmol/l	Down-titration should be considered in patients who develop a clinically significant decrease in renal function.

General Practitioner responsibilities
1 Monitor patient's overall health and well being.
2 Prescribe the drug treatment as described
3 Report any adverse events to the hospital specialist, where appropriate
4 Help in monitoring the progression of disease.
5 Alert the hospital of any suspected non-compliance with treatment.
6 Monitor blood pressure as per blood test monitoring frequency as advised

Patient's / Carer's role
1 Ask the specialist or GP for information, if he or she does not have a clear understanding of the treatment. 2 Tell the specialist or GP of any other medication being taken, including over-the-counter products. 3 Read the patient information leaflet included with your medication and report any side effects or concerns you have to the specialist or GP

BACK-UP ADVICE AND SUPPORT

Contact details	Specialist	Telephone No.	Email address:
Heart failure Nurses:	Kathryn Doherty Sharon Standing	(0118) 322 6638	Sharon.standing@royalberkshire.nhs.uk Kathryn.Doherty@royalberkshire.nhs.uk