Royal Surrey County Hospital NHS
NHS Foundation Trust

WORKING IN PARTNERSHIP WITH

Surrey (East Surrey CCG, Guildford & Waverley CCG, North West Surrey CCG, Surrey Downs CCG & Surrey Heath) Crawley CCG and Horsham & Mid-Sussex CCG

SHARED CARE Guideline – Amber Traffic Light Classification		
Name of medicine	Sacubitril valsartan	
Indication	Treatment of symptomatic chronic heart failure adult patients for with reduced ejection fraction, in line with TA388	
PCN policy statement: PCN 206-2016		
Author(s): Rachel Mackay, Carina Joanes **Organisation(s):** Guildford and Waverley CCG		
Version: 1.0	**PCN recommendation date: 06/2016**	**Review date: September 2018**

The Shared Care Guideline (SCG) is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface.
This AMBER shared care information sets out the patient pathway relating to this medicine and any information not available in the British National Formulary and manufacturer's Summary of Product Characteristics. Prescribing must be carried out with reference to those publications.
The SCG must be used in conjunction with the PCN agreed core roles and responsibilities stated in annex A.
An agreement notification form is included in annex B for communication of request for shared care from provider and agreement to taken on prescribing by primary care.

Roles and Responsibilities

Listed below are specific medicine/indication related responsibilities that are additional to those core roles and responsibilities that apply to all SCGs listed in annex A.

Consultant / Specialist - Initiation of sacubitril valsartan should only be initiated by heart failure specialists with access to a multidisciplinary heart failure team and in line with NICE TA388.

- Confirm that the patient meets NICE criteria for treatment with sacubitril valsartan:
  - with refractory/decompensated heart failure with New York Heart Association (NYHA) class II to IV symptoms and
  - with a left ventricular ejection fraction of 35% or less and a high BNP/proNT-BNP level of over 400 despite optimised standard CHF-treatment (ACEI/ARB/beta-blocker/MRA/diuretics)
  - who are already taking a stable dose of angiotensin-converting enzyme (ACE) inhibitors or angiotensin II receptor-blockers (ARBs) for at least 4 weeks
- Complete NICE checklist and send to GP with request for transfer of care

- Initiate, monitor and titrate to a stable dose (supply a minimum of three months of treatment: 8 weeks titration plus 4 weeks for transfer of care to the Primary Care Prescriber).
- Provide clear communication to the patient's Primary Care Prescriber to cease prescription of separate ACE/ARB therapy.

- Provide counselling to the patient to improve adherence and deal with any early adverse effects. Advise that this treatment has a minor influence on the ability to drive and use machines.
- To be available for advice if the patient's condition changes, and ensure that procedures are in place for the rapid re-referral of the patient by the Primary Care Prescriber.

Primary Care Prescriber

- Ensure use of sacubitril valsartan is in line with NICE TA 388, and that you have received sufficient information for safe transfer of care.
- Prescribe the drug treatment as described. It was noted at the Prescribing Clinical Network (PCN) that prescribing by the specialist will need to continue for at least 8 weeks to allow stabilisation to maximum tolerated dose, and allow a further 4 weeks to transfer care to the Primary Care Prescriber
- Monitor heart failure symptoms such as ankle swelling, referring to the specialist team where necessary
- Monitor blood pressure, renal function, liver function and electrolytes according to requirements and frequency set out in monitoring section. Action any abnormal result a necessary
- To emphasise the importance of adherence to sacubitril valsartan therapy and address any patient concerns

Patient Relatives & Carers

- As listed in PCN agreed core roles and responsibilities for the shared care of medicines – annex A

Key information on the medicine

Refer to the current edition of the British National Formulary (BNF), available at www.bnf.org, and Summary of Product Characteristics (SPC), available at www.medicines.org.uk for detailed product and prescribing information and specific guidance.

Background to use for the indications, including licence status:

Indication

Sacubitril valsartan▼ (Entresto®) is an angiotensin receptor neprilysin inhibitor, including both a neprilysin inhibitor (sacubitril) and an angiotensin II receptor blocker (ARB; valsartan).

It is licensed for treatment of symptomatic chronic heart failure adult patients for with reduced ejection fraction.
Funding is only available for patients who meet NICE criteria:
https://www.nice.org.uk/guidance/ta388/chapter/1-Recommendations

It will be considered as AMBER on the traffic light system

Dosage and Administration

As per British National Formulary (BNF), available at www.bnf.org, and Summary of Product Characteristics (SPC), available at www.medicines.org.uk

Monitoring
Blood samples may be taken at the patient's GP practice whenever this avoids a patient attendance in secondary care. Where the specialist is responsible for monitoring, they need to have the appropriate systems to capture the testing.

Monitoring requirements (including frequency) and appropriate dose adjustments	Responsible clinician
Pre-treatment: Serum potassium, renal function, liver function (AST/ALT), Presence of renal artery stenosis, measurement of left ventricular ejection fraction, and evaluation of NYHA disease classification, blood pressure	Specialist
Initiation: Serum potassium, renal function, liver function (AST/ALT), blood pressure	Specialist
Maintenance: (6-monthly unless poor renal or liver function, diabetes, or NYHA IV classification, in which case the frequency will be recommended by the specialist) Serum potassium, renal function, liver function (AST/ALT), blood pressure	Specialist until transfer of care agreed by primary care prescriber

Test	Abnormal Result	Action if Abnormal Result
Serum potassium	level greater than 5.4 mmol/l.	Contact specialist for advice
Blood pressure	<100mmHg	Contact specialist for advice
Renal Function	Moderate renal impairment	Dose adjustment may be needed at initiation, contact specialist for advice if renal function deteriorates.
	Severe renal impairment	Use with caution. Lower dose for initiation. Contact specialist for advice if renal function deteriorates.
Liver Function tests	Moderate hepatic impairment (Child–Pugh B classification) or with AST/ALT values more than twice the upper limit of the normal range.	Dose adjustment may be needed. Contact specialist for advice if liver function tests deteriorate.
	Moderate hepatic impairment (Child–Pugh B classification) or with AST/ALT values more than twice the upper limit of the normal range	Dose adjustment may be needed. Contact specialist for advice if liver function tests deteriorate.

Cautions, contraindications - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Adverse effects - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Drug interactions - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Support and Advice for the Primary Care

Name	Speciality	Telephone No.	Email address
Dr Mike Hickman	Cardiology – Heart failure lead	01483 571122 ext 6429	michael.hickman@nhs.net
Hospital Pharmacy	Medicines Information	01483 464120	rsc-tr.MedicinesInformation@nhs.net
Out of Hours	A&E Department RSCH	01483 571122	

Annex A: PCN agreed core roles and responsibilities for the shared care of medicines

Patients

- Make sure that you understand the treatment and ask for more information if needed
- Sharing concerns relating to treatment with whoever is prescribing this medicine for you
- Tell the prescriber of this medication about any other medication being taken, including over the counter products.
- Read the Patient information leaflet included with your medication and report any side effects or concerns you have to whoever is prescribing this medicine for you
- Expressing their preferences and wishes for how their treatment should be provided
- Consenting to treatment and agreeing to have aspects of their care, i.e. prescribing, transferred back to their Primary Care Prescriber
- Supported to know how to report any adverse effects to the specialist team, Primary Care Prescriber or other healthcare professional involved in their care, and how adverse effects can be managed.
- Informing the specialist team, Primary Care Prescriber or other healthcare professional if he or she has further questions or wants more information about the treatment.
- Sharing any concerns about their treatment and problems they are having taking their medicines with the specialist team, Primary Care Prescriber or other healthcare professional involved in their care.
- To be available for monitoring as required.
- To be available for follow up appointments as required.

Relatives & Carers

- To support the patient in fulfilling their roles and responsibilities as outlined above.

Consultant/Specialist

Good Prescribing Guidelines

- Be aware that if you recommend that a colleague, for example a junior doctor or GP, prescribes a particular medicine for a patient, you must consider their competence to do so. You must satisfy yourself that they have sufficient knowledge of the patient and the medicine, experience (especially in the case of junior doctors) and information to prescribe. You should be willing to answer their questions and otherwise assist them in caring for the patient, as required (Ref GMC).
- Be aware that if you delegate assessment of a patients' suitability for a medicine, you must be satisfied that the person to whom you delegate has the qualifications, experience, knowledge and skills to make the assessment. You must give them enough information about the patient to carry out the assessment required.
- Be aware that you are asking the Primary Care Prescriber to take full medico-legal responsibility for the prescription they sign(Ref GMC). For this reason the shared care guidelines (SCGs) are agreed at the PCN with input from specialists and Primary Care Prescribers, and, for individual patients, the patient's Primary Care Prescriber must agree to take over responsibility before transfer of care, before the patient is discharged from specialist care.
- Be aware of the formulary status and the traffic light classification of the medicine you are prescribing within the patient's CCG

- Assume clinical responsibility for the guidance given in the SCG, and where there is new information needed on the SCG to liaise with your Formulary Pharmacist who will facilitate an update via the PCN

Before initiating treatment

- Evaluate the suitability of the patient for treatment, including consideration of the patient's current medication and any significant interactions.
- Discuss and provide the patient with information about the reason for choosing the medicine, the likelihood of both harm and benefits, consequences of treatment, and check that their treatment choice is consistent with their values and preferences
- Advise patient of unlicensed status of treatment (including off-label use) if appropriate and what this may mean for their treatment.
- Undertake baseline monitoring and assessment.

Initiating and continuing treatment in secondary care

- Prescribe initial treatment and provide any associated training and counselling required.
- Inform the Primary Care Prescriber when initiating treatment so that the Primary Care Prescriber is aware what is being prescribed and can add to Primary Care Prescriber clinical record
- Continue to prescribe and supply treatment with appropriate monitoring until the patient's condition is stable; the patient is demonstrably benefiting from the treatment and is free from any significant side effects.
- At any stage of treatment, advising GP of concerns regarding monitoring or potential adverse effects of treatment

Transfer of care to Primary Care Prescriber

- Liaise with the Primary Care Prescriber to agree to share the patient's care and provide relevant accurate, timely information and advice.
- Only advise the patient that shared care will take place, and prescribing will be transferred, once the Primary Care Prescriber has agreed to share responsibility of the patient care, and that this has been confirmed in writing.
- If the Primary Care Prescriber feels unable to accept clinical responsibility for prescribing then the consultant must continue to prescribe the treatment to ensure consistency and continuity of care.
- Ensure that the patient (and carer/relatives) are aware of their roles and responsibilities under the SCG
- Provide sufficient information and training for the patient to participate in the SCG

Post transfer of care

- Follow up and monitor the patient at appropriate intervals.
- Advise Primary Care Prescriber if treatment dose changes or treatment is discontinued
  Inform Primary Care Prescriber if patient does not attend planned follow-up

<u>Primary Care Prescriber</u>

- Be aware of the formulary and traffic light status of the medicine you have been asked to prescribe.
- Be aware that Amber medicines have been assessed by the PCN as requiring careful transition between care settings but SCGs will be available to support safe transfer of care.

- It would be usual for Primary Care Prescribers to take on prescribing under a formal SCG. If you are uncertain about your competence to take responsibility for the patient's continuing care, you should seek further information or advice from the clinician with whom the patient's care is shared or from another experienced colleague. If you are still not satisfied, you should explain this to the other clinician and to the patient, and make appropriate arrangements for their continuing care.
- Be aware that if you prescribe at the recommendation of another doctor, nurse or other healthcare professional, you must satisfy yourself that the prescription is needed, appropriate for the patient and within the limits of your competence (Ref GMC).
- Be aware that if you prescribe, you will be responsible for any prescription you sign (Ref GMC).
- Keep yourself informed about all the medicines that are prescribed for the patient
- Be able to recognise serious and/ or frequently occurring adverse side effects, and what action should be taken if they occur.
- Make sure appropriate clinical monitoring arrangements are in place and that the patient and healthcare professionals involved understand them
- Keep up to date with relevant guidance on the use of the medicines and on the management of the patient's condition.
- Respond to requests to share care of patients in a timely manner, in writing (including use of form in annex B)
- Liaise with the consultant to agree to share the patient's care in line with the SCG in a timely manner.
- Continue prescribing medicine at the dose recommended and undertake monitoring requirements
- Undertake all relevant monitoring as outlined in the monitoring requirements section below, and take appropriate action as set out in this shared care guideline
- Monitor for adverse effects throughout treatment and check for drug interactions on initiating new treatments
- Inform the Consultant or specialist of any issues that may arise
- Ensure that if care of the patient is transferred to another prescriber, that the new prescriber is made aware of the share care guideline (e.g. ensuring the patient record is correct in the event of a patient moving practice).

All

Where it has been identified that a SCG requires update e.g. new information needed, liaise with the SCG author and/or your organisation PCN representative who will facilitate an update via the PCN.

Annex B: Shared care agreement notification form for medicines and indications approved as amber on the Surrey PAD or Crawley, Horsham and Mid-Sussex net formulary.

For the attention of the Practice Manager

FAX – Confirm you have the correct Safe Haven Fax Number before sending
E-mail – Confirm both sender and recipient e-mail addresses are nhs.net before sending

To:	[Recipient Name]	Fax:	[fax number]
From:	[Your Name]	Date:	[Click to select date]
Re:	[Subject]	Pages:	[number of pages]
cc:	[Name]		

[Notes]

Name of medicine	Sacubitril valsartan
Indication	Treatment of symptomatic chronic heart failure adult patients for with reduced ejection fraction, in line with TA388

Person removing form from fax machine	
Relevant patients Primary Care Prescriber available to action within 5 days (if not Trust needs to be informed on day of receipt of request)	Yes/ No
If Primary Care Prescriber is NOT available within 5 days, please communicate to the requesting specialist the date when the Primary Care Prescriber will be available	

Hospital/ Patient information		**Practice information**	
Consultant Making Request		Primary Care Prescriber Name:	
Consultant Speciality Details:		Practice:	
Patient Name:		I agree to undertake shared care:	
Patient NHS Number:		I do not agree to undertake shared care:	
Patient Hospital Number:		If NOT please give reasons:	
Patient DOB:		Signed:	
Drug Name/ Dose:		Date:	
Next Prescription Due:		Please return form to:	Specialist safe haven fax number
Discharge letter written and sent:			
Please refer to the Surrey PAD or Crawley, Horsham and Mid-Sussex net formulary for relevant shared care documents			

Primary Care Prescriber should reply within 5 days of receipt of this form indicating participation (or not) in shared care of the patient