Frimley Health and Care

Frimley Health ICS Medicines Optimisation Board

SHARED CARE Guideline – Amber Traffic Light Classification	
Name of medicine	Sacubitril valsartan tablets (Entresto®)
Indication (including whether for adults and/or children)	Heart Failure Reduced Ejection Fraction (HFrEF)
Author(s): Ann Parker **Organisation(s):** Frimley Health	
Date ratified by Frimley Health MOB (FH MOB):	25/8/2021 (update of original document approved at FH APC 23/11/2018)

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 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 whenever appropriate.
The SCG must be used in conjunction with the 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

Sacubitril valsartan will only be initiated by heart failure specialists (including nurses and pharmacists)

1. Assess the patient. Establish the diagnosis and assess the patient's ability to adhere to treatment.
2. Initiate treatment, monitor and titrate to a stable dose.
3. Contact the GP requesting shared care for the patient, including this shared care protocol
4. The Heart Failure Team will be available for verbal (or written) advice to the GP if the patient's condition changes or deteriorates. Following this advice GP's may refer patients back to the Heart Failure Team if this is required.
5. The Heart Failure Team will ensure the patient & carer(s) are given information regarding the treatment and a contact for the heart failure team if they have any concerns

General Practitioner's Responsibilities

1. Monitor patient's overall health and wellbeing.
2. Prescribe the drug once the patient has been stabilised and care transferred
3. Report any adverse events to the hospital specialist, where appropriate
4. Monitor blood results and action any abnormal results as necessary

Patient Relatives & Carers

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

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Key information on the medicine

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

Background to disease and use of medicine for the given indication
Sacubitril valsartan (Entresto®) is a neprilysin inhibitor (sacubitril) with an angiotensin II receptor blocker (ARB; valsartan). It is licensed for treatment of symptomatic chronic heart failure with reduced ejection fraction in adults. NICE TA 388 recommends sacubitril valsartan as an option for chronic heart failure patients who remain symptomatic despite optimal medical treatment. It is offered only in people:

1. With New York Heart Association (NYHA) class II to IV symptoms AND
2. With a left ventricular ejection fraction (LVEF) of 35% or less AND
3. Who are already taking an optimised and stable dose of angiotensin-converting enzyme inhibitor (ACEI) or angiotensin II receptor-blocker (ARB).

NICE TA 388 states that sacubitril valsartan must be initiated by a heart failure specialist with access to a multidisciplinary heart failure team. An example checklist to support implementation of the drug can be found using the following link: https://www.nice.org.uk/guidance/ta388/resources/example-checklist-2551344448

The Frimley Health APC has approved the use of sacubitril valsartan in patients who have LVEF <35% and who are tolerating optimal medical therapy (OMT) to include ACEI or ARB, Beta blocker and either spironolactone or eplerenone who:

1. Have had a recent unplanned heart failure admission without an obvious precipitating cause despite OMT
2. Are at risk of unplanned hospital admission or who have worsening symptoms despite OMT, but who have a predicted good/ stable prognosis.
3. Patients who remain heavily symptomatic and at risk from unplanned admission despite OMT i.e. NYHA III.

Under a shared care arrangement, treatment must be recommended by a consultant Cardiologist. Initiation and dose titration will be managed by the Heart Failure team. After the dose is stabilised, the patient can be transferred to the GP.

Evidence from PARADIGM-HF TRIAL (2014) demonstrated that patients with heart failure with reduced ejection fraction (LVEF<35%) and NYHA class II-IV treated with sacubitril/valsartan versus standard of care (ACEI- enalapril) had reduced mortality risk and reduced risk of heart failure hospitalisation. Patients who have severe heart failure, but who remain NYHA IV despite OMT should have access to quality palliative care support recognising that there is limited clinical experience with sacubitril/valsartan in this group within the PARADIGM trial and therefore specialist referral is highly recommended before initiation.

Indication
HFrEF (see restrictions above).

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Monitoring

Monitoring requirements including frequency and appropriate dose adjustments	Responsible clinician
Pre-treatment: • Established on ACEI or ARB • BNP • ECHO demonstrating LVEF<35% within last 12 months • Renal profile • LFTs • Blood pressure • Pulse • Weight	*Heart failure team*
Initiation: • Renal profile – one to two weeks after initiation or dose change • Blood pressure – at every clinic, minimum monthly • Pulse • Weight	*Heart failure team*
Maintenance: • Renal profile – monthly for three months once on a stable dose then six monthly unless acutely unwell • Blood pressure- 6 monthly • LFTs – annually from last blood test	*GP*
If dose change when on maintenance: • Renal profile – one to two weeks after dose change • Blood pressure-when reviewed minimum monthly • LFTs - annually	*GP* *Heart Failure Team*

Abnormal results – Actions to be taken

The GP may contact the specialist team for advice at any time if there are concerns.
The most commonly reported adverse reactions during treatment with sacubitril valsartan were hypotension, hyperkalaemia and renal impairment. For other side effects see SPC

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Side-effect/ test	Action
Angioedema & hypersensitivity	• If symptoms are severe this is a medical emergency and patients may require urgent hospital treatment. • Stop sacubitril valsartan and monitor until complete and sustained resolution of signs and symptoms has occurred.* It must not be re-administered. In cases of confirmed angioedema where swelling has been confined to the face and lips, the condition has generally resolved without treatment, although antihistamines have been useful in relieving symptoms.
Hyperkalaemia Serum K+ >5.4 mmol/L	• Stop concomitant medication that can increase serum potassium (e.g. potassium-sparing diuretics (spironolactone, eplerenone, triamterene, amiloride), mineralocorticoid antagonists, potassium supplements). • Consider reducing or stopping sacubitril valsartan.*
Asymptomatic low BP (Systolic BP <100mmHg)	Does not usually warrant a change in therapy, but BP requires monitoring and watch for worsening renal function.
Symptomatic hypotension (including dizziness, headache, syncope) (e.g. Systolic BP <100mmHg)	• Monitor BP, consider ambulatory monitoring if available • Consider dose adjustment of concomitant diuretics or antihypertensives (stop nitrates or calcium channel blockers first then consider reducing beta-blocker) • If dehydrated treat hypovolaemia. Symptomatic hypotension is more likely to occur if the patient has been volume-depleted, e.g. by diuretic therapy, dietary salt restriction, diarrhoea or vomiting. Giving fluids must be carefully weighed against the risk of volume overload. • Consider temporary down-titration or discontinuation of sacubitril valsartan.* • If affected this may limit the dose titration, possible or longer intervals between dose adjustments may be needed.
Renal impairment	An increase in urea, creatinine and K+ is to be expected after initiation/titration. If the increase is small and asymptomatic, no action is necessary If eGFR <60 ml/min consider: • Stopping concomitant nephrotoxic medication (e.g. NSAID's, diuretics, calcium channel blockers or nitrates). If on a diuretic reduce the dose to increase fluid & perfusion of the kidneys • Dose reduction of sacubitril valsartan. • Stopping sacubitril valsartan* (rarely needed unless GFR<30).
Persistent Dry cough	• Review aetiology of cough e.g. due to smoking, worsening heart failure/pulmonary oedema, respiratory disease • Review cough tolerability versus benefits of sacubitril/valsartan • May require discontinuation of treatment. If discontinuation is required refer patient back to heart failure team for re-assessment

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Anaemia, hypoglycaemia, vertigo, fatigue, asthenia, gastro-intestinal disorders (diarrhoea, nausea, gastritis)	• If severe consider seeking specialist advice
Severe hepatic impairment, biliary cirrhosis and cholestasis Moderate hepatic impairment (Child-Pugh B classification) or with AST/ALT values more than twice the upper limit of normal	• Contra-indicated • Caution- monitor, discuss with heart failure team.

*If sacubitril valsartan stopped consider restarting ACE I or ARB. If necessary seek advice from heart failure team. Allow 48 hour wash out period before restarting an ACE inhibitor.

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

Adverse effects and action to be taken (if appropriate) - 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

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Support and Advice Contact Details for Primary Care Prescribers:

Name	Speciality	Telephone No.
Dr Lydia Sturridge	Cardiology Frimley Park	Via switchboard 01276 604604
Dr Sofia Metaxa	Cardiology Wexham Park	Via switchboard 01753 633000
Dr Paresh Mehta	Cardiology Wexham Park	Via switchboard 01753 633000
Ann Parker	Pharmacy	01276 604604 bleep 400
Annabel Sturges	Heart Failure Nurse Specialist. Frimley Park	01276 604604 bleep 605
Preya Fakira	Cardiology pharmacist Wexham Park hospital	Via switchboard -01753 633000 bleep 2215 (Monday-Thursday)
Stephanie Murray	Heart Failure Nurse Specialist. Wexham Park	07775404609
Mark Stephens	Heart Failure Nurse Specialist. Wexham Park	07785996702
Medicines Information	Pharmacy	01276 604744

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

Patients
To be informed by initiating specialist, that the drug is a shared care drug and what this means.
Relatives and Carers
• To support the patient.
Consultant/ Specialist
Good Prescribing Guidelines • Be aware that if you recommend that a colleague, for example a junior doctor or Primary Care Prescriber, 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 Frimley Health Foundation Trust Area Prescribing Committee 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 Frimley Health Formulary. • Assume clinical responsibility for the guidance given in the SCG, and where there is new information needed on the SCG to liaise with a member of the Pharmacy team who will facilitate an update via the Frimley Health Foundation Trust Area Prescribing Committee. • Counsel patient on possible benefits, risks and side effects of the drug. **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. • Explain shared care status of drug and what this means to the patient.

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- 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 Primary Care Prescriber 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.
- 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

Primary Care Prescriber

- 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 Frimley Heath Area Prescribing Committee 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

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• 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's Frimley Health Foundation Trust Area Prescribing Committee representative who will facilitate an update at the Committee.

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Appendix 1

SHARED CARE PRESCRIBING GUIDELINE

: Shared care agreement notification form for medicines and indications approved as amber on the Frimley Health Foundation Trust Formulary

Agreement for transfer of prescribing to GP

Patient details

Name……..

Address……..

……..

……..

DOB……..

Hospital No……

NHS No……

Name of medicine	Sacubitril valsartan
Discharge Dose	
Indication	Heart Failure Reduced Ejection Fraction (HFrEF)

Hospital/ Patient information		**Practice information**	
Consultant Making Request		GP 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:	

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Discharge letter written and sent:			
Please refer to the Frimley Health Foundation Trust 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

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