SWL Integrated Medicines Optimisation Committee (IMOC)

Partner organisations include NHS South West London Integrated Care Board, "Place" Primary Care Networks (PCNs), Croydon Health Services NHS Trust, Epsom and St Helier University Hospitals NHS Trust, Kingston Hospital Foundation NHS Trust, St George's University Hospitals NHS Foundation Trust, South West London and St George's Mental Health NHS Trust, The Royal Marsden NHS Foundation Trust, South London and The Maudsley Foundation Trust (Croydon), Central London Community Healthcare NHS Trust, Your Healthcare CIC, Hounslow and Richmond Community Healthcare NHS Trust, Sutton Health and Care (Epsom and St Helier University Hospitals NHS Trust), Moorfields Eye Hospital NHS Foundation Trust (CHS/SGH Services), Local Pharmaceutical Committees and Local Medical Committees.

Local authorities: Croydon Council, Kingston Council, Merton Council, Richmond Upon Thames London Borough Council, Sutton Council, Wandsworth London Borough Council

Associates: NHS Surrey Heartlands Integrated Care Board, London Ambulance Service

Meeting date: (IMOC admin)	19 February 2025		
Agenda item: (IMOC admin)	10.2	**Attachment(s):** (IMOC admin)	Enc F2
Title of paper:	Sacubitril valsartan (Entresto®) for Heart Failure with Reduced Ejection Fraction – Information Sheet		
Author and contributors:	Laura Bijman (Heart Failure Specialist Pharmacist at St George's Hospital, NHS SWL). Natalie Curley (Lead Pharmacist (Quality), Medicines Optimisation Team (Medicines & Safety), NHS SWL Gautam Narayan (GP Principal - Merton Medical Practice & Clinical Lead for Cardiology and Metabolic Health Network – Primary Care, NHS SWL, SWL Integrated Care System) Document content adapted with permission from South East London IMOC approved documents (available at SEL IMOC - Cardiovascular disease guidance - NHS South East London) - Heart Failure – Sacubitril valsartan FAQ - Heart Failure – Sacubitril valsartan patient pathway		
Paper type: (Delete as appropriate)	Treatment Pathway / Guideline / **Information Sheet**		
For: (Delete as appropriate)	Note amendment to formulary (prescribing status change to Amber 2)		
Interests to be declared for:	*List any companies, for which any interests should be declared by members in relation to this paper at the meeting* *Nil*		
CORE20 PLUS 5:	*Indicate if in line with the CORE20 PLUS 5 priorities* NHS England » Core20PLUS5 – An approach to reducing health inequalities for children and young people NHS England » Core20PLUS5 (adults) – an approach to reducing healthcare inequalities *Not applicable – not a clinical area of focus*		

Executive Summary:

1. **Introduction – basis for pathway / guideline**

This information sheet is an update to the existing prescribing pathway for sacubitril valsartan within the current (last updated 2021) NHS SWL guidance on pharmacological management of heart failure (HF) which includes clinical guidance on prescribing of sacubitril valsartan for patients with reduced ejection fraction (HFrEF).
To support a change in formulary prescribing status of sacubitril valsartan from Amber 3 to Amber 2 as below, this Information Sheet updates the criteria for, and mechanism of, transfer of prescribing responsibility from HF specialists and primary care, and roles and responsibilities of both groups in the care of patients prescribed this medication.

2. **Pathway Changes – outline changes to existing pathway / guideline**

Existing NHS SWL formulary prescribing status (RAG rating) for sacubitril valsartan is Amber 3 (HF specialist initiation, up-titration & stabilisation on maximum tolerated dose for minimum 1 month before specialist transfers prescribing to primary care with Transfer of Care documentation).
Proposed change is to Amber 2 status (HF specialist initiation, up-titration & stabilisation on maximum tolerated dose before specialist transfers prescribing to primary care as documented in discharge letter or clinic letter, including an individual management plan).

This is to prevent interruptions in therapy from reliance on transfer of care forms; furthermore this harmonises the sacubitril valsartan formulary status in SWL with SEL.

This formulary prescribing status change has been approved by the SWL Joint Formulary Committee (February 2025) pending review at the SWL Integrated Medicines Optimisation Committee (IMOC)

The Information Sheet document submitted for IMOC approval to support the above approval is an information sheet to outline roles and responsibilities of clinicians prescribing for patients prescribed this medication in the context of the proposed Amber 2 formulary status. This is adapted from analogous clinical guidance/information sheets produced and approved by South East London IMOC in 2023.

The NHS SWL guidance on pharmacological management of heart failure is under review and when updated will also reflect these changes in transfer of prescribing responsibility.

3. **Clinical Implications**

This Information Sheet and change in sacubitril valsartan formulary prescribing status to Amber 2 is not intended to change clinical use of sacubitril valsartan. This medication will still be initiated by HF specialists, only for clinically appropriate patients, who will undergo titration and monitoring by HF teams until stabilised on a maximum tolerated maintenance dose.

Transfer of prescribing responsibility from the HF specialist to the GP will be via clinical correspondence in the form of a clinic letter or discharge letter, to include an individual management plan (plans for specialist follow up and/or ongoing management in community, frequency of ongoing monitoring and any other relevant clinical information).

HF specialists remain available for consultation through established channels in the event of queries arising from primary care regarding ongoing prescribing of this medication or overall management of HF patients.

Sacubitril valsartan is recommended for prescribing in the NHS by NICE technology appraisal 388 (27 April 2016): Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction (LVEF ≤35%), which it states should be started "*on the advice of a HF specialist with access to a multidisciplinary HF team. Dose titration and monitoring should be done by the most appropriate team member as defined in NICE's guidance on chronic HF in adults [by a HF specialist or in primary care by the most appropriate team member].*"

This technology appraisal is reflected in NICE guidance 106 (2018) *Chronic heart failure in adults: diagnosis and management*.

Sacubitril valsartan is also given a Class I Level of evidence B recommendation in European Society of Cardiology 2021 Guidelines for the diagnosis and treatment of acute and chronic HF, for patients with LVEF ≤40%, stating "*Sacubitril/valsartan is recommended as a replacement for an ACE-I in patients with HFrEF to reduce the risk of HF hospitalization and death"*

4. Financial Implications

The list price of sacubitril valsartan (Entresto®) is £91.56 per 56 tablets (28 day supply) (BNF online 02/2025) with a 1 year supply costing £596.78.
The proportion of patients prescribed this drug in primary versus secondary care (or in total throughout NHS SWL ICS) is not expected to change significantly on account of this formulary status change and accompanying guidance document.

5. Consultation Summary

This document has been written and approved by the HF specialist team at St George's Hospital, NHS SWL, adapted with permission from analagous South East London IMOC approved documents as linked above.

The contents of the Information Sheet and the formulary prescribing status change has been discussed with stakeholders in the secondary and primary care cardiology networks (December 2024), discussed at LMC (January 2025), and subsequently circulated /comments invited from clinicians in primary and secondary care across SWL primary and secondary care cardiovascular networks.

Summary: *(What is the IMOC being asked to do and why)*

1. For information - sacubitril valsartan Information Sheet to support JFC approval of the prescribing status (RAG rating) change from Amber 3 to Amber 2

Accompanying papers (please list):

1. Sacubitril valsartan (Entresto®) for Heart Failure with Reduced Ejection Fraction – Information Sheet
2. January 25 JFC Outcome letter – Sacubitril valsartan

NHS
South West London

Sacubitril valsartan (Entresto®) for Heart Failure with Reduced Ejection Fraction – Information Sheet

Target audience

Primary and secondary care clinicians in NHS South West London (NHS SWL) managing patients with heart failure (HF) with reduced ejection fraction (HFrEF).

Summary

- This document covers the use of sacubitril valsartan (Entresto®) in patients with HFrEF. It should be utilised in conjunction with the NHS SWL HF pathway and SWL pharmacological management of HF guidance.
- Sacubitril valsartan is an angiotensin receptor-neprilysin inhibitor (ARNI). It is licensed and approved by NICE in technology appraisal 388 (TA388) for use in the management of HF in patients with reduced ejection fraction (LVEF ≤35%) who remain symptomatic despite a stable dose of ACEI or ARB.

Recommendations

- Sacubitril valsartan is to be initiated by the patient's specialist HF team (AMBER 2 on NHS SWL formulary). The patient will be monitored by the HF team until titrated to the maximum tolerated dose. Prescribing of sacubitril valsartan will then transfer to primary care once stabilised on the dose.
- Transfer of prescribing responsibility is to be communicated to primary care via clinic letter or discharge letter including an individual management plan (this replaces transfer of care forms).

Roles and responsibility

HF specialist team responsibility

- Following a shared decision by a heart failure specialist (nurse, pharmacist or doctor) with the patient, considering benefits and risks, contra-indications and side effects (see SPC and SWL pharmacological management of HF) initiate sacubitril valsartan for symptomatic chronic HFrEF according to NICE TA 388.
- Monitor patient at initiation and following dose changes until up-titrated to the highest tolerated dose of sacubitril valsartan on which the patient is stable (stable renal function and blood pressure (BP), no side effects), prior to transfer of prescribing responsibility to primary care.
- Complete discharge letter or outpatient letter requesting transfer of prescribing responsibility, which should include:
    - Indication for therapy, dose.
    - Individual management plan.
    - Plans for follow up.
    - Assessment results upon stabilisation on maintenance dose: renal function and electrolytes and BP.
    - Details of HF specialist team for advice/support.
- Secondary care HF team to support community HF nursing team with clinical advice regarding dose titration and prescriptions as appropriate

- Supply at least 4 weeks of sacubitril valsartan at transfer of prescribing (exception applies for patients requiring blister packs – primary care may be asked to prescribe earlier).
- Continue to follow up the patient for further optimisation of HF management as clinically indicated.

Primary care responsibility

- Continue prescribing sacubitril valsartan at the recommended maintenance dose after initiation and stabilisation and following communication from the heart failure team as above (AMBER 2 on SWL formulary – transfer of care via clinic/discharge letter, to include individual management plan).
- Remove ACEI or ARB from repeat prescriptions, add sacubitril valsartan to repeat prescriptions and communicate changes with the patient's community pharmacy especially for blister pack patients to reduce the risk of co-prescribing errors and potential acute kidney injury (AKI) and/or hyperkalaemia.
- Review medication and seek HF specialist advice if concerned about:
    - Systolic BP ≤ 95 mmHg with symptomatic hypotension
    - Angioedema (stop sacubitril valsartan)
    - Pregnancy/breastfeeding (sacubitril valsartan is contra-indicated)
    - Serum potassium >5.4mmol/L (may need to consider discontinuation or dose reduction)
    - Severe hepatic impairment, biliary cirrhosis or cholestasis (contraindicated with Child-Pugh C cirrhosis)
    - eGFR declines to <30ml/min or increased serum creatinine by >50% or CrCl reduced by >50% from baseline
    - Dehydration, worsening HF symptoms, fluid overload/weight gain
    - The patient is experiencing psychiatric events as an adverse effect
- Follow up in primary care with 6-monthly medical review recommended by NICE CG 106 for stable HF patients.

Prescribing and monitoring guidance

- Recommended initial dose is 49/51 mg twice daily and the dose is doubled at 2 to 4 weeks to the target dose 97/103 mg twice daily if tolerated.
- An initiation dose of 24/26 mg twice daily is indicated in patients with hypotension (SBP 100 to 110 mmHg), moderate renal impairment (eGFR 30-60 ml/min) or moderate hepatic impairment (ALT/AST ≥2x ULN).
- Never prescribe an angiotensin converting enzyme inhibitor (ACE-I) or angiotensin II receptor blocker (ARB) at the same time as sacubitril valsartan.
    - If the patient is already taking an ACEI: STOP ACEI therapy for 36 hours before starting sacubitril valsartan.
    - Patients already taking ARBs may start sacubitril valsartan on the day after stopping ARB therapy.
- The monitoring requirements of sacubitril valsartan are the same as an ACE-I or ARB. Baseline blood pressure, heart rate and a renal profile will be checked prior to initiation and at 2-4 weeks following each dose change.
- See SWL pharmacological management of HF guidance and summary of product characteristics for further prescribing and monitoring information.

References/resources

- NICE technology appraisal 388: Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction. NICE; 27 April 2016
- NICE guidance 106: Chronic heart failure in adults: diagnosis and management. NICE; 12 September 2018
- Summary of Product Characteristics: Entresto 24/26 mg film-coated tablets. Novartis Pharmaceuticals UK Ltd; 4 September 2023
- South West London Guidance on Pharmacological Management of Heart Failure. South West London Integrated Medicines Optimisation Committee (SWL IMOC) – NHS South West London; 2021

Adapted from

- Sacubitril/Valsartan (Entresto®) Frequently Asked Questions (FAQs). South East London Integrated Medicines Optimisation Committee (SEL IMOC) – NHS South East London; 2023
- Sacubitril/valsartan (Entresto®) prescribing patient pathway for heart failure in South East London. SEL IMOC – NHS South East London; 2023

Document History

Version: V 1.0

Author: **NHS SWL Cardio Renal Metabolic Network**
Approved by: NHS Southwest London Integrated Medicines Optimisation Committee (IMOC)
Approval date: **xxxx**
Review Date: 2 years from approval date or sooner where appropriate.
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South West London Integrated Care System

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Acute Provider Collaborative

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05.02.2025

SWL Joint Formulary Committee – Decision Letter

Dear Natalie

Drug name: Sacubitril/Valsartan

Thank you for submitting the above application to the SWL Joint Formulary Committee. It was considered by the committee on 30 January 2025.

This application proposes a change in formulary prescribing status of sacubitril–valsartan (Entresto) from Amber 3 (transfer of care form required) to Amber 2 (communication of transfer of care via clinic/discharge letter). This is to preventing interruptions in therapy from reliance on the transfer of care forms. It has been agreed with the SWL Cardiac Network (December 2024) and the Local Medical Committee (January 2025). An information sheet (prescribing pathway) is being drafted and will be submitted to SWL IMOC, following JFC approval.

Decision: Approved
Prescribing status: Amber 2 (Initiation by a specialist, stabilisation for a specified time, then continuation in primary care)
Prescriber restrictions: N/A
Shared care required: No
Drug tariff status: In-tariff **Next steps**

This medicine also requires review at the SWL Integrated Medicines Optimisation Committee (IMOC) before the formulary decision can be implemented. The JFC decision will be forwarded directly to IMOC for consideration at their next meeting (usually within 1 month), and no action is required from you in this respect. Should any questions or concern be raised at IMOC that will impact on implementation, you will be contacted directly.

Yours sincerely,

Dr Andrew Hitchings
Chair, SWL Joint Formulary Committee

c.c. SWL Joint Formulary Committee Team