

Statement on the use of Sacubitril/Valsartan (Entresto[®]) for the treatment of symptomatic chronic heart failure with reduced ejection fraction

1. The CMSCN Sacubitril/Valsartan (Entresto[®]) Task and Finish Group supports the use of Sacubitril/Valsartan as per NICE TA 388, that is:

Sacubitril/Valsartan is recommended as an option for treating symptomatic chronic heart failure with reduced ejection fraction, only in people:

- with New York Heart Association (NYHA) class II to IV symptoms **and**
- with a left ventricular ejection fraction of 35% or less **and**
- who are already taking a stable dose of angiotensin-converting enzyme (ACE) inhibitors or angiotensin II receptor-blockers (ARBs).

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 a heart failure specialist.

2. Key Groups in whom Sacubitril/Valsartan should especially (but not exclusively) be considered as an alternative to ACE/ARB therapy include;
 - NYHA class II or III
 - Recent Hospitalisation for heart failure (within last 6 months)
3. Patients being considered for Sacubitril/Valsartan should be on *optimal** first line heart failure therapy. **Optimal therapy is defined as beta blocker, mineralocorticoid receptor antagonist and ACE/ARB titrated to maximum tolerated dose.* (Current NICE 2018 chronic heart failure pathway positions Sacubitril/Valsartan as a second-line specialist option).
4. B-type natriuretic peptide (BNP) is not a suitable biomarker of heart failure in patients treated with Sacubitril/Valsartan because it is a neprilysin substrate.
5. The group acknowledges potential barriers to implementation include variance in how heart failure services are commissioned locally and capacity issues within secondary/tertiary care for accepting referrals. Local discussions need to take place to ensure patients have access to this NICE approved treatment.
6. A key concern exists around patient safety when switching from ACE/ARB therapy to Sacubitril/Valsartan. Poor and/or delays in communication between healthcare interfaces may expose the patient to the risk of concurrent therapy. Healthcare professionals should ensure that patients are fully aware of this risk and take steps to mitigate it by utilisation of patient alert cards and timely and adequate communication to the GP and community pharmacist.
7. Mindful of the point above, healthcare professionals should pay particular attention to those patients who receive medications via compliance aids (blister packs) to ensure additional appropriate steps are taken to avoid concurrent therapy.
N.B. Sacubitril/Valsartan cannot be placed in blister packs

8. The following patients should not be considered for Sacubitril/Valsartan;
- ACE inhibitor/ARB naïve
 - ARB intolerant (if ACE intolerant, should try ARB first)
 - Serum potassium greater than 5.4mmol/Litre
 - End stage renal disease
 - eGFR less than 30mls/min (local decision - these patients were excluded from the trial)
 - Systolic blood pressure less than 100mmHg
 - Severe hepatic impairment
 - A left ventricular ejection fraction of more than 35%