# Example checklist for consideration when implementing NICE technology appraisal guidance on sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction

Grey boxes indicate criteria recommended in the NICE technology appraisal. The [electronic medicines compendium](https://www.medicines.org.uk/emc/medicine/31244#PRODUCTINFO) (EMC) and clinical advice from [experts planning the implementation](http://www.nice.org.uk/guidance/ta388/resources) of this NICE technology appraisal have been used to add further detail to this checklist.

# Service delivery model

## Governance

|  |  |
| --- | --- |
| Is the drug being started by a heart failure specialist with access to a multidisciplinary heart failure team? |  |
| Has the most appropriate member of the multidisciplinary heart failure team responsible for monitoring and dose titration been identified?  |  |

## Drug initiation

|  |  |
| --- | --- |
| Has the patient been taking a stable dose of ACE inhibitors or ARBs up to this time? |  |
| If the patient has been taking an ACE inhibitor, has there been **at least** a 36-hour washout period? |  |
| If the patient has been taking an ARB has it been stopped? |  |
| Has the patient been advised of the [common and very common side effects](https://www.medicines.org.uk/emc/medicine/31244) (including hypotension, renal impairment and hyperkalaemia; see table 1, Section 4.8 EMC) and how to report side effects for the [yellow card scheme](https://www.medicines.org.uk/emc/medicine/31244#UNDESIRABLE_EFFECTS).  |  |

## Maintenance

|  |  |
| --- | --- |
| Have the plans for ongoing management in relation to sacubitril valsartan been communicated with the GP? If so by what means?* local shared care protocol
* written letter detailing initiation of the drug and management plans.
 |  |

# Patient selection

## Exclusion criteria

If any of the following patient criteria are true, the patient should **not** be offered sacubitril valsartan.

|  |  |
| --- | --- |
| **Criteria** | **Tick if true** |
| Symptomatic chronic heart failure with reduced ejection fraction of greater than 35%. |  |
| Symptomatic chronic heart failure with reduced ejection fraction and NYHA class I symptoms. |  |
| Not taking a stable, optimised dose of ACE inhibitors or ARBs for at least 4 weeks. |  |
| A history of angioedema related to previous ACE inhibitor or ARB therapy. |  |
| Systolic blood pressure less than 100 mmHg.  |  |
| Severe hepatic impairment, biliary cirrhosis and cholestasis (Child–Pugh C classification). |  |
| End-stage renal failure. |  |
| Hereditary or idiopathic angioedema. |  |
| Taking aliskiren-containing products and either Diabetes mellitus or renal impairment (eGFR less than 60 ml/min/1.73 m2).  |  |
| Pregnant or breastfeeding. Not recommended during the first trimester of pregnancy or when breast-feeding, and contraindicated during the second and third trimesters of pregnancy. |  |
| Taking direct renin inhibitors such as aliskiren. |  |
| Taking ACE inhibitors or ARBs for another indication which means they cannot be stopped. |  |
| Less than 18 years old. |  |

## Precautions and patient considerations

If any of the following precautions are relevant to the patient, detail the action to be taken below.

| **Precautions**  | **Y / N** | **Action** |
| --- | --- | --- |
| Serum potassium level greater than 5.4 mmol/l. |  |  |
| Moderate renal impairment. Dose adjustment may be needed at initiation. |  |  |
| Severe renal impairment. Use with caution. Lower dose for initiation. |  |  |
| 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. |  |  |
| Renal artery stenosis. Monitor renal function. |  |  |
| Driving vehicles or operating machines; has a minor influence on the ability to drive and use machines. |  |  |
| NYHA class IV. Caution. |  |  |
| Elderly patients. The dose should be in line with the renal function of the elderly patient. |  |  |
| Co-administration of sacubitril valsartan:* Statins. Sacubitril may reduce some drugs absorption by liver cells through effects on membrane transporters (OATP1B1 and OATP1B3). Exercise caution. Reduction in statin dose maybe required.
* PDE5 inhibitors including sildenafil. Co-administration is associated with a significantly greater blood pressure reduction. Exercise caution.
* Potassium. Concomitant use of potassium-sparing diuretics, mineralocorticoid antagonists, potassium supplements, salt substitutes containing potassium or other agents (such as heparin) may increase serum potassium, and serum creatinine. Monitor serum potassium.
* NSAID, including selective COX-2 inhibitors in elderly patients, volume-depleted patients (including those on diuretic therapy), or patients with compromised renal function. Monitor renal function.
* Lithium. Concomitant administration is not recommended. If necessary, monitor serum lithium levels.
* Furosemide. Urinary excretion of sodium may be reduced.
* Nitrates. May reduce heart rate.
* Inhibitors of OATP1B1, OATP1B3, OAT3 (rifampicin, ciclosporin), OAT1 (tenofovir, cidofovir) or MRP2 (ritonavir). May increase the systemic exposure of sacubitril or valsartan.
* Metformin. May reduce levels of metformin. Monitor clinically.
 |  |  |

Signed………………………. Designation……………………………….Date………….

This example checklist should be used alongside the [guidance](https://www.nice.org.uk/guidance/ta388).