

1	<p>Treatment & Condition</p> <p>Sacubitril valsartan for the treatment of symptomatic chronic heart failure with reduced ejection fraction.</p>
2	<p>Associated appraisal body & Summary of ruling</p> <p>NICE technology appraisal guidance [TA388] (April 2016)</p> <p>Sacubitril valsartan is recommended as an option for treating symptomatic chronic heart failure with reduced ejection fraction, only in people:</p> <ul style="list-style-type: none"> • 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). <p>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 the most appropriate team member as defined in NICE’s guideline on chronic heart failure in adults: management.</p> <p>This guidance is not intended to affect the position of patients whose treatment with sacubitril valsartan was started within the NHS before this guidance was published. Treatment of those patients may continue without change to whatever funding arrangements were in place before this guidance was published until they and their NHS clinician consider it appropriate to stop.</p> <p>The committee agreed there was a lack of evidence in people who have not previously had ACE inhibitors or ARBs, noting that 99% of patients in the PARADIGM-HF trials were taking ACE inhibitors or ARBs at entry to the study. The committee concluded that sacubitril valsartan should only be offered, in place of ACE inhibitors or ARBs, to patients who are symptomatic despite already taking a stable dose of ACE inhibitors or ARB.</p>
3	<p>Number of people in Northern Ireland expected to take up service/therapy <i>(including new cases per year)</i></p> <p>The table below is based on the Resource Impact Report that accompanies NICE TA388</p>

Estimated number of people eligible for treatment with sacubitril valsartan in Northern Ireland

Population	Proportion	No. of people
Total NI population		1,840,498
People with heart failure ^a	0.76%	14,036
People with heart failure with reduced ejection fraction ^b	72.00%	10,106
People with heart failure with reduced ejection fraction and NYHA class II to IV symptoms ^c	71.10%	7,185
People with heart failure with reduced ejection fraction and NYHA class II to IV symptoms, with a left ventricular ejection fraction of 35% or less ^c	59.50%	4,275
People with heart failure with reduced ejection fraction and NYHA class II to IV symptoms, with a left ventricular ejection fraction of 35% or less and taking ACE inhibitor/ARB ^b	85.95%	3,674
People having sacubitril from year 5 onwards ^d	60.00%	2,204

It is estimated that approximately 3,700 people are eligible for sacubitril valsartan each year.

From year 2020/21, once uptake has reached 60%, it is estimated that 2,200 people will receive sacubitril valsartan each year. These assumptions recognise that as this is a new drug it will be used with caution initially.

4	Patient Access Scheme availability										
	Not applicable										
5	Costs <i>(before PAS if applicable)</i>										
5.1	Drug cost per patient per annum (for new and prevalent cases)										
	<table border="1" style="width: 100%;"> <tr> <td>Maximum daily dosage: [200mg (97mg sacubitril/103mg valsartan) twice daily] Tablets per day</td> <td style="text-align: right; vertical-align: bottom;">400 2</td> </tr> <tr> <td>Unit cost 200mg (97mg sacubitril/103mg valsartan): 56 pack tablets</td> <td style="text-align: right; vertical-align: bottom;">£91.56</td> </tr> <tr> <td>Cost per tablet</td> <td style="text-align: right;">£1.64</td> </tr> <tr> <td>Cost per day</td> <td style="text-align: right;">£3.27</td> </tr> <tr> <td>Cost per patient per year</td> <td style="text-align: right;">£1,193.55</td> </tr> </table>	Maximum daily dosage: [200mg (97mg sacubitril/103mg valsartan) twice daily] Tablets per day	400 2	Unit cost 200mg (97mg sacubitril/103mg valsartan): 56 pack tablets	£91.56	Cost per tablet	£1.64	Cost per day	£3.27	Cost per patient per year	£1,193.55
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5.2	<p>Infrastructure costs per patient per annum</p> <p>As part of current standard practice, initiation of ACEi or ARB treatment requires titration and therefore the cost for dose titration and monitoring associated with sacubitril valsartan is not considered incremental over ACEi or ARB. There are no additional tests or investigations needed for sacubitril valsartan compared to ACEi or ARB.</p>																																																																																																																																																																	
5.3	<p>Current in year costs</p> <p>The current in year cost is estimated to be £393k.</p>																																																																																																																																																																	
5.4	<p>Recurrent overall costs per annum before PAS (including additional costs)</p> <p>The table below is based on the Resource Impact Report that accompanies NICE TA388.</p> <table border="1" data-bbox="240 741 1449 1984"> <tr> <td>Number of people eligible for treatment</td> <td>3,674</td> <td>3,674</td> <td>3,674</td> <td>3,674</td> <td>3,674</td> <td>3,674</td> </tr> <tr> <td>Treatment Profile (%)</td> <td>Baseline</td> <td colspan="5">Financial years</td> </tr> <tr> <td></td> <td></td> <td>2016/17</td> <td>2017/18</td> <td>2018/19</td> <td>2019/20</td> <td>2020/21</td> </tr> <tr> <td>People using ACE-i</td> <td>85.00%</td> <td>76.50%</td> <td>64.76%</td> <td>54.64%</td> <td>44.52%</td> <td>34.40%</td> </tr> <tr> <td>People using ARBs</td> <td>15.00%</td> <td>13.50%</td> <td>11.24%</td> <td>9.36%</td> <td>7.48%</td> <td>5.60%</td> </tr> <tr> <td>People using Sacubitril valsartan</td> <td>0.00%</td> <td>10.00%</td> <td>24.00%</td> <td>36.00%</td> <td>48.00%</td> <td>60.00%</td> </tr> <tr> <td>Reduced hospital admission rate</td> <td>0.00%</td> <td>-3.71%</td> <td>-3.71%</td> <td>-3.71%</td> <td>-3.71%</td> <td>-3.71%</td> </tr> <tr> <td>Treatment Profile (Patient Nos)</td> <td>Baseline</td> <td colspan="5">Financial years</td> </tr> <tr> <td></td> <td></td> <td>2016/17</td> <td>2017/18</td> <td>2018/19</td> <td>2019/20</td> <td>2020/21</td> </tr> <tr> <td>People using ACE-i</td> <td>3,123</td> <td>2,811</td> <td>2,379</td> <td>2,007</td> <td>1,636</td> <td>1,264</td> </tr> <tr> <td>People using ARBs</td> <td>551</td> <td>496</td> <td>413</td> <td>344</td> <td>275</td> <td>206</td> </tr> <tr> <td>People using Sacubitril valsartan</td> <td>0</td> <td>367</td> <td>882</td> <td>1,323</td> <td>1,764</td> <td>2,204</td> </tr> <tr> <td></td> <td>3,674</td> <td>3,674</td> <td>3,674</td> <td>3,674</td> <td>3,674</td> <td>3,674</td> </tr> <tr> <td>Treatment Cost (excluding VAT) £000s</td> <td>Baseline</td> <td colspan="5">Financial years</td> </tr> <tr> <td></td> <td></td> <td>2016/17</td> <td>2017/18</td> <td>2018/19</td> <td>2019/20</td> <td>2020/21</td> </tr> <tr> <td>People using ACE-i</td> <td>99</td> <td>89</td> <td>75</td> <td>63</td> <td>52</td> <td>40</td> </tr> <tr> <td>People using ARBs</td> <td>48</td> <td>43</td> <td>36</td> <td>30</td> <td>24</td> <td>18</td> </tr> <tr> <td>People using Sacubitril valsartan</td> <td>0</td> <td>439</td> <td>1,052</td> <td>1,579</td> <td>2,105</td> <td>2,631</td> </tr> <tr> <td></td> <td>146</td> <td>570</td> <td>1,163</td> <td>1,672</td> <td>2,180</td> <td>2,689</td> </tr> <tr> <td>Existing Baseline Funding £000s</td> <td></td> <td>146</td> <td>146</td> <td>146</td> <td>146</td> <td>146</td> </tr> <tr> <td>Net additional funding required £000s</td> <td></td> <td>424</td> <td>1,017</td> <td>1,525</td> <td>2,034</td> <td>2,542</td> </tr> <tr> <td>Savings from reduced hospital admission £000s</td> <td></td> <td>31</td> <td>74</td> <td>112</td> <td>149</td> <td>186</td> </tr> <tr> <td>Net resource impact (excluding VAT) £000s</td> <td></td> <td>393</td> <td>943</td> <td>1,414</td> <td>1,885</td> <td>2,356</td> </tr> </table>	Number of people eligible for treatment	3,674	3,674	3,674	3,674	3,674	3,674	Treatment Profile (%)	Baseline	Financial years							2016/17	2017/18	2018/19	2019/20	2020/21	People using ACE-i	85.00%	76.50%	64.76%	54.64%	44.52%	34.40%	People using ARBs	15.00%	13.50%	11.24%	9.36%	7.48%	5.60%	People using Sacubitril valsartan	0.00%	10.00%	24.00%	36.00%	48.00%	60.00%	Reduced hospital admission rate	0.00%	-3.71%	-3.71%	-3.71%	-3.71%	-3.71%	Treatment Profile (Patient Nos)	Baseline	Financial years							2016/17	2017/18	2018/19	2019/20	2020/21	People using ACE-i	3,123	2,811	2,379	2,007	1,636	1,264	People using ARBs	551	496	413	344	275	206	People using Sacubitril valsartan	0	367	882	1,323	1,764	2,204		3,674	3,674	3,674	3,674	3,674	3,674	Treatment Cost (excluding VAT) £000s	Baseline	Financial years							2016/17	2017/18	2018/19	2019/20	2020/21	People using ACE-i	99	89	75	63	52	40	People using ARBs	48	43	36	30	24	18	People using Sacubitril valsartan	0	439	1,052	1,579	2,105	2,631		146	570	1,163	1,672	2,180	2,689	Existing Baseline Funding £000s		146	146	146	146	146	Net additional funding required £000s		424	1,017	1,525	2,034	2,542	Savings from reduced hospital admission £000s		31	74	112	149	186	Net resource impact (excluding VAT) £000s		393	943	1,414	1,885	2,356
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	<p>The recurrent overall cost is estimated to be £393k in 2016/17 rising to £2.36m per year from 2020/21.</p> <p>The treatment will be initiated in secondary care. Estimated costs are £33k in 2016/17 rising to £196k in 2020/21.</p>
5.5	<p>Opportunities for cost savings and how these will be secured</p> <p>Treatment with sacubitril valsartan should be started by a heart failure specialist. Patients advised to commence sacubitril valsartan at a hospital outpatient appointment in NI will have all of their drug supply provided via primary care. Patients who start treatment following a hospital admission will have a 28-day supply provided from secondary care. The proportion of patients who will commence treatment during an inpatient admission is not known. However, use of this drug is expected to result in a reduction in hospital admissions overall and there are not expected to be any additional net costs to the secondary care sector.</p>
6	<p>Expected implementation period</p> <p>There are no barriers to immediate implementation anticipated.</p>
7	<p>Commissioning arrangements</p> <p>As this treatment is initiated by a heart failure specialist, TA 388 will be commissioned in secondary care however all prescribing costs will have to be met by the primary care prescribing budget.</p> <p>Shared care protocols will need to be developed between primary and secondary care for monitoring arrangements.</p>
8	<p>Monitoring arrangements</p> <p>The prescribing trends for this drug will be monitored by medicines management advisers where appropriate. The Medicines Management Commissioning Team will monitor trends in the use of this drug.</p>
9	<p>DHSSPS Legislative/Policy Caveats</p> <p>This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.</p>