NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Resource impact report:
Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction (TA388)

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Summary

NICE has recommended sacubitril valsartan as an option for treating symptomatic chronic heart failure (see sections 1.1, 1.2 and 1.3 of the guidance).

Around 108,000 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 an ACE inhibitor/ARB are likely to be eligible for sacubitril valsartan.

Based on clinical expert opinion annual uptake is estimated to be around 64,500 people from 2020/21 onwards, recognising this is a new drug and it will be used with caution initially.

Treatment with sacubitril valsartan is estimated to cost around £1,200 per person per year.

The table below shows the estimated annual cost of implementing this technology for the population of England, an estimated £12.6 million in 2016/17 rising to £69.0 million in 2020/21 plus VAT where applicable. This is based on the uptake included in the resource impact model assumptions.

Details	2016/17	2017/18	2018/19	2019/20	2020/21
Population having sacubitril valsartan each year	12,900	25,800	38,700	51,600	64,500
Cost impact before savings and excluding VAT (£000s)	13,500	29,800	44,700	59,500	74,400
Cost savings from reduced hospital admissions (£000s)	−900	−2,200	−3,300	−4,300	−5,400
Net cost impact (£000s)	12,600	27,600	41,400	55,200	69,000

1 Introduction

1.1 This report looks at the resource impact of implementing the NICE guidance on sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction in England.

1.2 The guidance states that sacubitril valsartan is recommended as an option for treating symptomatic chronic heart failure in certain people (see sections 1.1, 1.2 and 1.3 of the guidance).

1.3 This report is supported by a resource impact template. The template aims to help organisations in England, Wales and Northern Ireland plan for the financial implications of implementing the NICE guidance by amending the variables in the blue cells.

1.4 This technology is commissioned by clinical commissioning groups (CCGs). Providers are NHS hospital trusts and GPs in primary care.

1.5 Because sacubitril valsartan was made available in the NHS through the early access to medicines scheme, NHS England has indicated that this guidance will be implemented 30 days after final publication. Sacubitril valsartan is the first drug commissioned by CCGs to be approved under the early access to medicines scheme. Previously, all the other drugs available via the access to medicines scheme were cancer drugs and commissioned by NHS England.

2 Background and epidemiology of chronic heart failure

2.1 Heart failure is generally defined as the inability of the heart to supply sufficient blood flow to meet the body's needs. Heart failure may be associated with reduced left ventricular ejection fraction, where the left pumping chamber’s ability to pump is impaired.

2.2 Symptoms of heart failure are classified by the New York Heart Association (NYHA) system from class I (no limitations) to class IV (inability to carry out any physical activity without discomfort), and commonly include breathlessness, fatigue and ankle swelling. Quality of life is affected by the physical limitations imposed by the symptoms.

2.3 Around 410,800 people were recorded as having heart failure in England in 2014/15 (QOF 2014–15). Of these, 72% (295,800) had heart failure with reduced ejection fraction (British Society of Heart Failure 2015).

Table 1 Number of people eligible for treatment in England

Population	Proportion (percentage of previous row)	Number of people
Total population of England		53,865,817
People with heart failure[a]	0.76%	410,783
People with heart failure with reduced ejection fraction[b]	72.00%	295,764
People with heart failure with reduced ejection fraction and NYHA class II to IV symptoms[c]	71.00%	210,288
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%	125,121
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 an ACE inhibitor/ARB[b]	85.95%	107,541
People having sacubitril valsartan from year 5 onwards[d]	60.00%	64,525

a. 0.76; Health and Social Care Information Centre. Quality and Outcomes Framework (QOF) for April 2014 - March 2015, England.
b. British Society of Heart Failure. National Heart Failure Audit, April 2013—March14. Published on 20 October 2015.
c. Company submission.
d. Based on clinical expert opinion.

Abbreviations: NYHA, New York Heart Association.

2.4 We estimate that approximately 108,000 people are eligible for sacubitril valsartan each year.

2.5 From year 2020/21, once uptake has reached 60%, we estimate that 64,500 people will have sacubitril valsartan each year, recognising this is a new drug and it will be used with caution initially.

3 Assumptions made

3.1 Table 1 shows the population assumptions used in the resource impact template. Table 2 shows the assumptions of current and future uptake and table 3 shows assumed annual treatment costs.

Table 2 Current and future uptake assumptions

Technology	Current uptake (%)	Future uptake (%)[b]
Angiotensin-converting enzyme inhibitors[a]	85.0	34.4
Angiotensin II receptor blockers[a]	15.0	5.6
Sacubitril valsartan	0.0	60.0

a. British Society of Heart Failure. National Heart Failure Audit, April 2013—March14. Published on 20 October 2015.
b. From year 5 onwards, based on clinical expert opinion.

Table 3 Annual treatment cost assumptions

Technology	Treatment cost
Angiotensin-converting enzyme inhibitors[a]	£32
Angiotensin II receptor blockers[b]	£87
Sacubitril valsartan[b]	£1,194
Heart failure – hospitalisation[d]	£2,698

a. Based on weighted average annual treatment costs of 4 different drugs (enalapril, ramipril, perindopril and lisinopril).
b. Based on weighted average annual treatment costs of 3 different drugs (losartan, candesartan and valsartan).
c. Based on a dosage of 200 mg twice daily.
d. 2016/17 National tariff. See resource impact template for more details.

3.2 There are no additional tests or investigations needed for sacubitril valsartan compared with existing therapies.

3.3 The cost-effectiveness analysis for sacubitril valsartan showed benefit over ACEi on heart failure hospitalisation as well as cardiovascular and non-cardiovascular hospitalisations. The resource impact model used all-cause hospitalisation rates as per the company economic model (ACEi 35.52% and sacubitril

valsartan 31.81%) to estimate potential savings from reduced hospitalisations.

4 Resource impact

4.1 Table 4 shows the estimated annual cost associated with implementing the guidance for the population of England. We estimate the resource impact to be £12.6 million in 2016/17 rising to £69.0 million per year from 2020/21 plus VAT where applicable, which is equivalent to £23,000 rising to £127,000 per 100,000 population.

4.2 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.

4.3 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. Also there are no additional tests or investigations needed for sacubitril valsartan compared to ACEi or ARB.

4.4 Where the drug is prescribed in secondary care VAT is payable giving a maximum cost of £84.4 million after 5 years. Continued prescribing may take place in primary care where VAT is not payable. See Figure 1.

4.5 The template allows users to adjust VAT accordingly.

Table 4 Estimated resource impact of implementation for the population of England

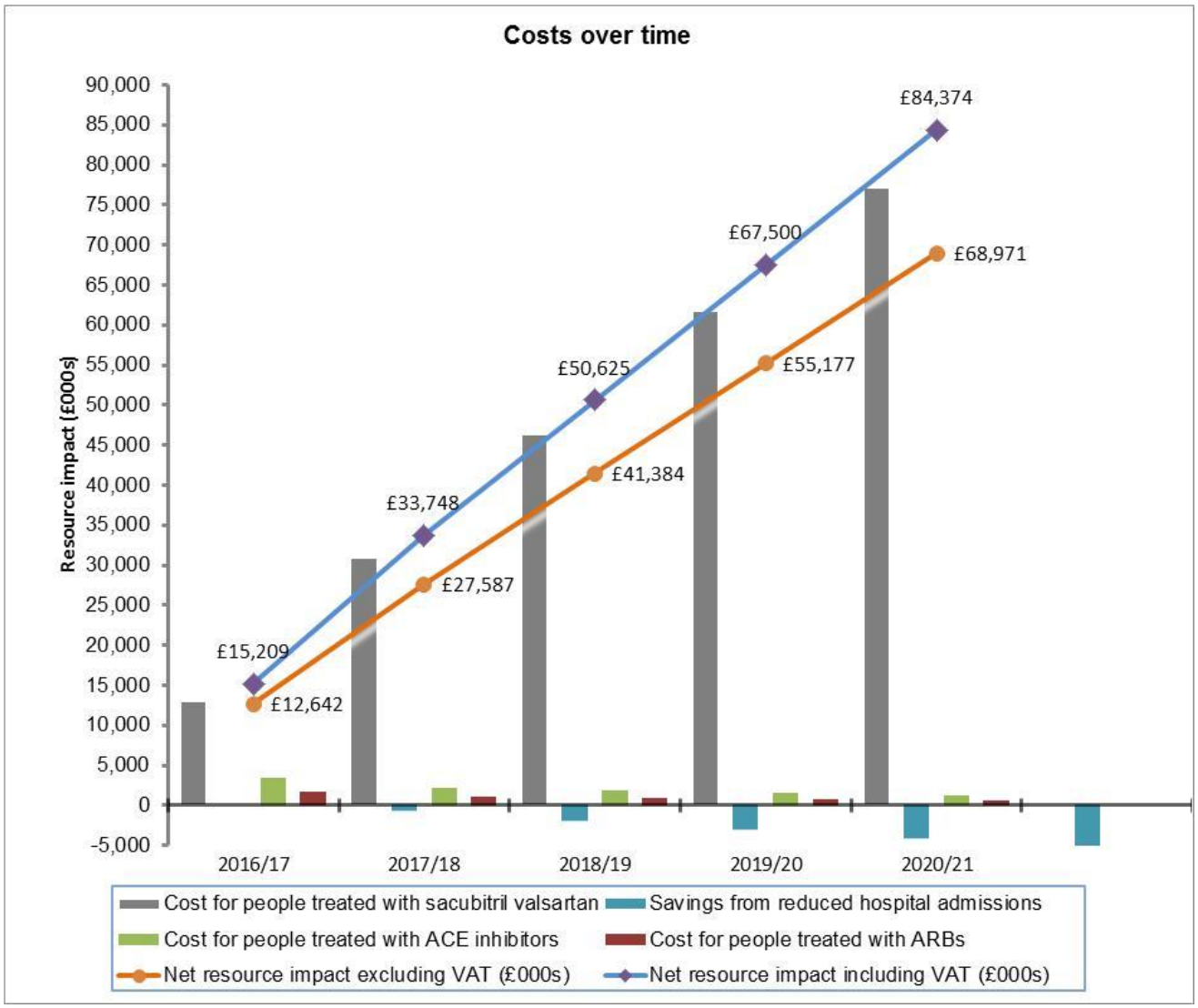
Details	2016/17	2017/18	2018/19	2019/20	2020/21
Population having sacubitril valsartan each year	12,900	25,800	38,700	51,600	64,500
Cost impact before savings and excluding VAT (£000s)	13,500	29,800	44,700	59,500	74,400
Cost savings from reduced hospital admissions (£000s)	−900	−2,200	−3,300	−4,300	−5,400
Net cost impact (£000s)	12,600[a]	27,600	41,400	55,200	69,000

a. Section 7(6) of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires clinical commissioning groups, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this appraisal within 3 months of its date of publication. Because sacubitril valsartan was made available in the NHS through the early access to medicines scheme, NHS England has indicated that this guidance will be implemented 30 days after final publication. Therefore implementation is assumed to start in June 2016. The resource impact has been adjusted to reflect 10 months of resource use in 2016/17.

4.6 We assume that uptake of sacubitril valsartan will rise from 12% in 2016/17 to 60% in 2020/21, assuming a steady increase by 12% each year.

4.7 The resource impact template uses these assumptions to estimate the 5-year cost to commissioners from 2016/17. However, actual uptake will depend on local implementation strategies. Organisations are encouraged to use the resource impact template to estimate the local costs over time. Figure 1 shows how the base uptake estimates in 4.6 would affect organisations, based on sacubitril valsartan being used for the population of England.

Figure 1: Resource impact over time using base uptake assumptions, 2016/17 to 2020/21



5 Savings and benefits

5.1 Based on the company submission the introduction of sacubitril valsartan may reduce the costs of hospital admissions because of heart failure.

5.2 Using base uptake assumptions in section 4.6 and hospitalisation rates in section 3.3, potential savings are estimated at around £0.9m in 2016/17, rising to £5.4 million from year 5 onwards.

5.3 Sacubitril valsartan also improves both overall mortality and cardiovascular mortality, which may lead to additional cost savings.

6 Sensitivity analysis

6.1 Varying the proportion of eligible people having sacubitril valsartan from a minimum of 50% to a maximum of 70% changes the resource impact from £57.6 million to £80.2 million.

6.2 Varying the proportion of people with heart failure with NYHA class II to IV symptoms and a left ventricular ejection fraction of 35% or less from a minimum of 55% to a maximum of 65% changes the resource impact from £63.8 million to £75.3 million.

6.3 Varying the proportion of people with heart failure with NYHA class II to IV symptoms and a left ventricular ejection fraction of 35% or less who are already having ACE inhibitors or ARBs from a minimum of 80.00% to a maximum of 85.95% changes the resource impact from £64.2 million to £69.0 million.

7 Implications for commissioners

7.1 This technology is commissioned by CCGs.

7.2 Sacubitril valsartan for treating symptomatic chronic heart failure falls within the programme budgeting category 9: problems of circulation.

8 References

1. Health and Social care Information Center. Quality and Outcomes Framework (QOF) for April 2014 - March 2015, England.
2. NHS (2015) Enhanced Tariff Option for 2015/16 [accessed January 2016].
3. British Society of Heart Failure. National Heart Failure Audit, April 2013— March14. Published on 20 October 2015.

About this resource impact report

This resource impact report accompanies the NICE technology appraisal guidance on sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction and should be read in conjunction with it. See terms and conditions on the NICE website.

This report is written in the following context

This report represents the view of NICE, which was arrived at after careful consideration of the available data and through consulting healthcare professionals. The report is an implementation tool and focuses on the recommendations that were considered to have a significant impact on national resource use.

Assumptions used in the report are based on assessment of the national average. Local practice may be different from this, and the impact should be estimated locally.

Implementation of the guidance is the responsibility of local commissioners and providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this costing tool should be interpreted in a way that would be inconsistent with compliance with those duties.