NICE National Institute for Health and Care Excellence

Adoption support resource – insights from the NHS

Implementation support

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1 Introduction

This resource has been developed to provide practical information and advice relating to NICE technology appraisal guidance on sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction.

It is intended to be used by both clinical staff and staff that manage and commission heart failure services who are planning to implement the guidance and start using this technology.

NICE's adoption and impact programme worked with NHS clinicians to share their learning and experiences of planning the adoption of this guidance.

The information presented is complementary to the guidance and was not considered by the technology appraisal committee when developing its recommendations.

Sacubitril valsartan is an angiotensin receptor neprilysin inhibitor, including both a neprilysin inhibitor (sacubitril) and an angiotensin II receptor blocker (ARB; valsartan). Both sacubitril and valsartan lower blood pressure.

The learning gained is presented as series of examples of current practice. They are not presented as best practice but as real-life examples of how NHS sites have planned the introduction of this technology.

2 Summary of NICE recommendations

NICE technology appraisal guidance on sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction[1] recommends it as an option for treating symptomatic chronic heart failure 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 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 the most appropriate team member as defined in NICE's guideline on chronic heart failure in adults: management.

[1] The 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 for them before this guidance was published until they and their NHS clinician consider it appropriate to stop (recommendation 1.3).

3 Current practice

There is a NICE care pathway, clinical guideline and quality standard for the management of chronic heart failure in adults. NICE has also developed several pieces of technology appraisal[2] and interventional procedure guidance[3] related to managing chronic heart failure. The European Society of Cardiology has also published a guideline on heart failure.

The NICE guideline on chronic heart failure in adults recommends both ACE inhibitors/ARBs and beta-blockers licensed for heart failure as first-line pharmacological treatments for heart failure with left ventricular systolic dysfunction. Clinical experts (involved in development of this resource and the guidance) detailed that clinical practice is broadly in line with the NICE guideline in terms of first-line treatment (that is, ACE inhibitors or ARBs are taken concomitantly with a beta blocker), with the addition of an aldosterone antagonist.

According to the technology appraisal guidance, sacubitril valsartan would be prescribed after this initial pharmacological management stage in the care pathway.

[2] Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure (2014) NICE technology appraisal guidance 314 and ivabradine for treating chronic heart failure (2012) NICE technology appraisal guidance 267.

[3] Insertion and use of implantable pulmonary artery pressure monitors in chronic heart failure (2013) NICE interventional procedure guidance 463 and partial left ventriculectomy (the Batista procedure) (2004) NICE interventional procedure guidance 41.

4 Tips from the NHS for managing the introduction of sacubitril valsartan

The NHS contributors to this resource considered the following to be important:

- Establish a working group including a consultant cardiologist, a heart failure nurse specialist, a pharmacist, a general practitioner and a clinical commissioning group representative (see implementation group).
- Agree locally the patient pathways (for example shared care agreements) and protocols for patient consideration, patient selection, initiation, titration, monitoring and ongoing management.
- Establish effective communications systems to ensure that healthcare professionals responsible for patients taking sacubitril valsartan are aware of any potential implications.

5 How to implement the guidance

Clinicians' experiences have been used to develop practical suggestions on how to implement the NICE technology appraisal guidance on sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction. Local organisations will need to assess the applicability of the learning from the examples of current practice, taking into consideration the time, resources, clinical factors and costs of an implementation programme.[4]

Project management

This technology can be best adopted using a project management approach. NICE has produced the into practice guide which includes a section on what organisations need to have in place to support the implementation of NICE guidance in this way.

Implementation group

The first step is to form an implementation group that will advise on the technology and manage any changes in practice. When establishing this group, consider:

- establishing the geographical area of the working group
- patient flows and pathways
- whether the group may be specific to an individual NHS organisation or may work across a region, such as a cardiovascular network
- making use of already established heart failure groups or prescribing liaison groups.

In order to implement this guidance in an effective and sustainable way, contributors to this resource suggested the following membership of the team:

- Clinical champion(s): could be a senior clinician with an interest in heart failure (consultant cardiologist). They should have the relevant knowledge and understanding to be able to drive the project, answer any clinical queries and champion implementation at a senior level.

- Commissioning lead(s): perhaps the chronic conditions lead and or local commissioning pharmacist. They will have the responsibility for assessing the cost impact on the drugs budget and existing heart failure services, liaising with the CCG board, raising awareness in primary care about the introduction of this new medication and agreeing reallocation or additional resource.
- Other stakeholders or staff, which may include:
  - consultant cardiologists with an interest in heart failure from each of the prescribing centres (where the group is regional), including local hospitals
  - heart failure specialist nurses
  - GPs including those with a special interest in cardiology
  - cardiac pharmacists or community pharmacists representing the regional pharmacy committee, joint formulary group or local prescribing committee, or local medical committees
  - community providers of heart failure services
  - patient groups.

Direct membership from all stakeholders may not be needed, but contributors' experience suggests that clear communication, engagement and agreement between all stakeholders is important for successful implementation.

Early questions that the team may wish to consider are:

- What will be the cost impact of implementing this guidance in our area?
- Who within our area can prescribe this drug?
- How will patients be referred for consideration of this drug?
- How will we ensure patients started on this drug are titrated and monitored appropriately?
- What communications systems do we need to set up to ensure that patients' GPs and other clinical staff are aware of patients having this drug and the potential side effects?

Care pathway mapping

Sites planning implementation of this guidance acknowledged that several factors would need to be considered and agreed locally between stakeholders:

- Local referral pathways for patients who are not currently under the direct care of the specialist heart failure service.
- Capacity of the heart failure team to manage a potential increase in referrals.
- How consideration and initiation of the drug will fit in with current care pathways for people with heart failure.
- Clarifying responsibilities, perhaps through shared care agreements for:
  - assessing and counselling people being considered for treatment
  - initiating treatment and informing relevant healthcare professionals that the patient is taking this drug
  - providing titration and associated monitoring
  - ongoing prescription and follow-up once the patient is established.

Several models of care are being considered by the sites that contributed to this resource.

Assessing, counselling and initiation

- Develop patient information in line with the NICE guideline on medicines optimisation. Ensure that healthcare professionals can share information with patients about:
  - potential risks and benefits of changing (because this drug is recommended for people on a stable dose of ACE inhibitors or ARBs, some patients may be unsure or unhappy to change their current regimen)
  - what procedure to undertake for the washout period
  - provision of any relevant alert cards
  - reporting of side effects for the yellow card scheme.

- Identify those responsible. This may be a consultant cardiologist or secondary care heart failure nurse specialists under the guidance of the consultant cardiologist. Consider planning for the heart failure nurse specialist with prescribing qualifications to take over initial prescribing once the team feels more experienced in prescribing the drug.
- Develop systems for ensuring an appropriate washout period for ACE inhibitors. The electronic medicines compendium states that sacubitril valsartan must not be started until at least 36 hours after taking the last dose of ACE inhibitor therapy. After the prescription for sacubitril valsartan has been issued and collected, patients could return to clinic to take the initial dose under the supervision of the heart failure nurse specialist (or other heart failure specialist) who can confirm if the washout period has been adhered to. Experts considered a 48-hour washout period to be practical. ARB treatment should also be stopped, but a washout period is not stipulated.
- See the complementary example checklist for details of factors to consider when commencing sacubitril valsartan.

Titration and associated monitoring

- Establish responsibility for monitoring and drug titration. The guidance recommends this should be done by the most appropriate team member (of the specialist multidisciplinary heart failure team), as defined in NICE's guideline on chronic heart failure in adults: management. At the initial stage of implementation this is likely to be the specialist heart failure clinic. Review the patient 2 weeks after drug initiation at either a consultant or heart failure nurse clinic for assessment of renal function through blood results (which would have been taken before the appointment), blood pressure and patient-reported tolerance and, if appropriate, increase to maximum dose. Following the increase to maximum dose, review patients 2 weeks later to check blood results, blood pressure and patient-reported tolerance.

Ongoing prescription and follow-up

- Establish a locally agreed period over which the specialist heart failure team will provide the prescription, and when the ongoing prescribing will be handed over to primary care. Agreements ranged from 1 month to 3 months after initiation. The agreement for ongoing prescribing in primary care was seen as essential for effective implementation.

- Following stabilisation on a maximum tolerated dose, patients are monitored at least 6-monthly (if appropriate to clinical status). Depending upon current local pathways and patient suitability, this may be in primary care.

Patient selection

This guidance does not recommend sacubitril valsartan for all people with reduced ejection fraction. Before starting sacubitril valsartan it is anticipated that patients would be having care in line with current practice. See the complementary example checklist for details of factors to consider when starting sacubitril valsartan.

In order to ensure the use of the drug in a cost-effective manner, in line with the appraisal, NHS organisations may want to develop local protocols with locally agreed definitions of:

- Whether previous assessments of ejection fraction can be used or if a new echo is needed. In defining this locally, sites will want to take the following into account in relation to the last measurement: timescales (no longer than 12 months since last measurement), the patient's condition; length of time on stable doses of optimal medical therapy; and other management since last measurement. For NYHA class assessment, it was felt that this could be done at the time of the prescribing decision.
- A stable dose of ACE inhibitors or ARBs. In developing the guidance, the committee concluded that sacubitril valsartan should be started in people who are already having a stable, optimised dose of an ACE inhibitor or an ARB. In the main trial on which the guidance was based, a stable dose was taken to mean at least 4 weeks.
- Appropriate patient and clinical factors which should be considered to account for the contraindications and considerations detailed by the company and in the electronic medicines compendium. These may include blood pressure, kidney function, potassium levels and history of angio-odema, and could be detailed in shared care protocols or initiation checklists.

Measuring success and monitoring implementation

The electronic medicines compendium states that 'This medicinal product is subject to additional monitoring'. Healthcare professionals are asked to report any suspected adverse reactions through the yellow card scheme.

In order to demonstrate that the guidance has been adopted in an effective way it may be

helpful to take measurements before, during and after implementation. Some of these measures will not be routinely collected and sites must consider a data collection methodology that is appropriate to the service. Sites contributing to this resource considered this to be particularly important, because they plan to implement the guidance while considering the learning and experience of patients for whom sacubitril valsartan was prescribed.

Suggested measures include:

- retrospective data collection of the number of patients for whom the drug would have been suitable (time period for data collection to be agreed locally depending upon aims)
- prospective data collection about the number of patients started on the drug, an assessment of its suitability and whether they had appropriate follow-up
- complications associated with abruptly stopping ACE inhibitors or ARBs during the washout period
- adverse reactions
- patients' blood pressure response to starting the drug.

Resource impact

This technology is commissioned by clinical commissioning groups. Providers are NHS hospital trusts and GP practices.

NICE has published a resource impact report and resource impact template that can be used by NHS commissioners and providers to understand better the local costs associated with adopting the guidance. The national assumptions used in the template can be altered to reflect local circumstances.

To help estimate the number of potentially suitable patients, organisations could consider counting the specialist heart failure service caseload and engaging with GPs to assess the proportion of patients who are in primary care.

Education and awareness raising

Once agreements for implementation have been established, sites that contributed to this resource suggest implementing an education and awareness-raising exercise with colleagues in primary care and healthcare professionals who are not specialised in heart failure but who may be prescribing drugs for the patient. This would include information about the drug, side effects, concomitant use with other drugs (in particular ACE inhibitors), patient suitability, the locally agreed protocols and side effect reporting for the yellow card scheme. The heart failure nurses who have close links with primary care were seen as an effective way of achieving this.

Consider a system for ensuring that GP letters are sent out on the same day that a patient started taking sacubitril valsartan, with initiation highlighted in bold.

[4] Section 5.1 of the technology appraisal guidance states that '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.'

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7 About this resource

This resource accompanies NICE technology appraisal guidance on sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction. It was developed using the NICE adoption and impact programme: process guide for adoption support resources for health technologies. It is an implementation tool and discusses and summarises the experiences reported by NHS sites planning to adopt this technology and shares the learning that took place.

It is the responsibility of local commissioners and providers to implement the guidance at a local level, being mindful of their duty to advance equality of opportunity and foster good relations. Nothing in this document should be interpreted in a way that would be inconsistent with this.

Click here for more information about the adoption and impact programme.

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