NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Costing report:

Implementing the NICE guidance on rifaximin for preventing episodes of overt hepatic encephalopathy (TA337)

Published: March 2015

This costing report accompanies the NICE Technology appraisal: rifaximin for preventing episodes of overt hepatic encephalopathy (available online at http://guidance.nice.org.uk/TA337).

Issue date: March 2015

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 with healthcare professionals. It should be read in conjunction with the NICE guideline. The report is an implementation tool and focuses on the recommendations that were considered to have a significant impact on national resource utilisation.

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/or 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

National Institute for Health and Care Excellence
Level 1A
City Tower
Piccadilly Plaza
Manchester M1 4BT

www.nice.org.uk

1 Introduction

1.1 Technology appraisals cover the use of new and existing medicines and treatments within the NHS in England. 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.

1.2 The Welsh Assembly Minister for Health and Social Services has issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 3 months of the guidance being published

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

1.4 This technology is commissioned by clinical commissioning groups (CCGs). Providers are NHS hospital trusts.

2 Background of the technology appraisal

2.1 Hepatic encephalopathy is a reversible neuropsychiatric syndrome caused by an accumulation of toxins in the bloodstream that are normally removed by the liver (Guest et al. 2014). Rifaximin decreases intestinal production and absorption of ammonia, which is thought to be responsible for the neurocognitive symptoms of hepatic encephalopathy, thereby delaying the recurrence of acute episodes.

2.2 Hepatic encephalopathy is defined based on the severity of clinical symptoms of mental deterioration using the Conn grade. It may be classified as covert or minimal (Conn grade 0 or 1) or overt (Conn grade 2, 3 or 4). When people are in remission or have minimal hepatic encephalopathy, their condition may be managed at home under secondary care. However if a person has an acute overt episode they are often admitted to hospital for treatment.

2.3 The current standard of care is treatment with lactulose although lactulose is not licensed for reducing the recurrence of episodes of overt hepatic encephalopathy.

2.4 The estimated eligible population for rifaximin for preventing episodes of overt hepatic encephalopathy is expected to be approximately 12,000 people for the population of England.

2.5 Expert clinical opinion suggests that rifaximin is effective in reducing the recurrence of hepatic encephalopathy episodes and is well tolerated. Treatment with rifaximin may improve quality of life, prevent readmissions to hospital and reduce morbidity and carer burden.

2.6 Expert clinical opinion suggests that people may continue to use rifaximin until death or until they have a liver transplant.

3 Guidance

3.1 The guidance states that:

Rifaximin is recommended, within its marketing authorisation, as an option for reducing the recurrence of episodes of overt hepatic encephalopathy in people aged 18 years or older*.*

4 Assumptions made

4.1 The costing model makes the following assumptions:

- The number of people with recurrent episodes of hepatic encephalopathy in England is uncertain. A study by Fleming et al. (2008) showed that in 2001 the prevalence of cirrhosis was estimated to be 76 per 100,000 population. This is equivalent to around 31,900 people in England.
- Evidence suggests that overt hepatic encephalopathy occurs in 30–45% of people with cirrhosis (Wolf, 2014). Using a midpoint of 37.5%, the estimated eligible population for rifaximin could be around 12,000 people in England.
- Expert clinical opinion suggests that the only comparator available is lactulose. In the clinical trial presented by the company (Norgine), 91% of people had treatment with lactulose. Therefore, of the eligible population it is assumed that 91% of people (approximately 11,000 people in England) will opt for future treatment.
- Rifaximin became available in January 2013. Norgine estimate there are around 2,300 people (21% of the treated population) currently taking rifaximin. Norgine estimate by year 3, the number of people taking rifaximin will rise to 40% of the treated population. Expert clinical opinion confirmed Norgine's estimates of current and future use are reasonable.
- Of the treated population taking rifaximin, it is assumed 91% of people take rifaximin and lactulose treatment and 9% take rifaximin only.
- The annual cost of rifaximin and concomitant lactulose has been calculated by multiplying the cost listed in the February 2015 electronic drug tariff by the number of times it is expected to be taken.
- The estimated dose of rifaximin is 550 mg twice daily.
- In the modelling, the estimated dose of lactulose equates to an average of 3.51 cups per day when it is taken on its own compared with 3.14 cups per day when taken with rifaximin.

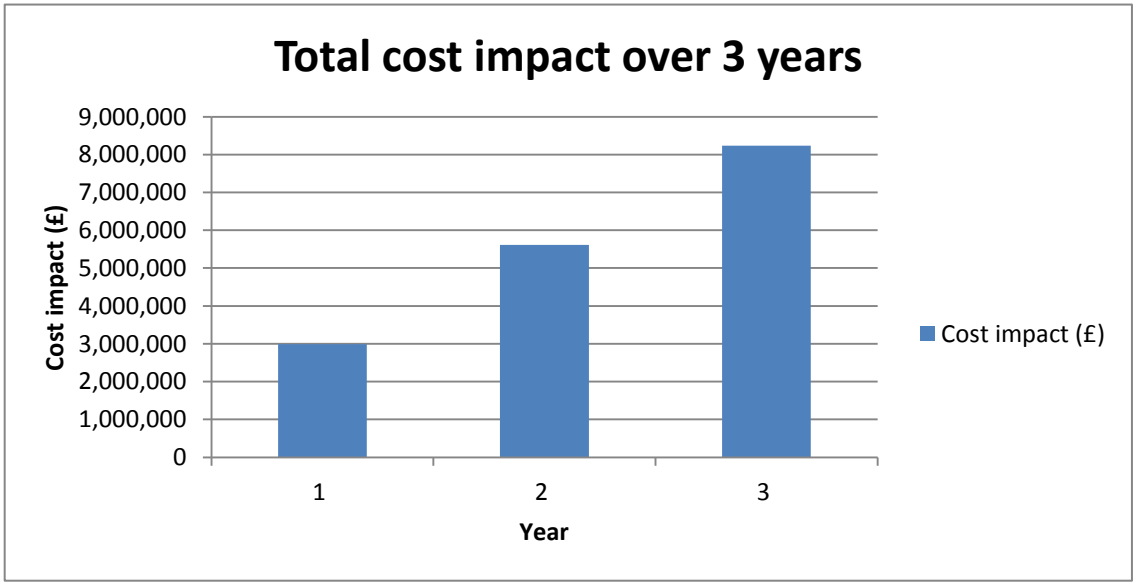
- Annual costs of treatment have been calculated. However, some people may not remain on rifaximin for a full year.
- The associated costing template allows for savings due to a reduction in hospital admissions which should be assessed locally.
- From year 3 onwards costs are assumed to remain constant.

5 Costing summary

5.1 The cost associated with implementing the guidance is estimated as £8.2 million from year 3 onwards for the population of England, based on the standard assumptions in the model. Table 1 below shows the cost impact over the next 3 years.

Table 1 Total cost of treatment for the population of England over 3 years

	Current Year	Year 1	Year 2	Year 3
Net cost impact (£000)	0	**2,992**	**5,613**	**8,234**



5.2 For a more detailed look at the costs, please refer to the costs over time section in the costing template.

6 Savings and benefits

6.1 Expert clinical opinion suggests that rifaximin is effective in reducing the recurrence of hepatic encephalopathy episodes and is well tolerated. Avoiding hospital admissions is very important for people with hepatic encephalopathy and may benefit their mental health as well as the health of their carers and families. Data are not available to quantify these potential savings. Expert clinical opinion suggests that rifaximin may also improve quality of life for people in remission.

6.2 Expert clinical opinion suggests that rifaximin may reduce the length of stay in hospital. For providers this could represent a potential productivity saving and for commissioners any bed-days prevented could also lead to savings. The average cost to the NHS of an inpatient bed day is around £240 (national tariff 2014/15).

6.3 Expert clinical opinion suggests lactulose is not well tolerated. Adding rifaximin to current treatment with lactulose may result in reduced doses of lactulose which may improve adherence to treatment and improve quality of life.

7 Implications for commissioners

7.1 Rifaximin for preventing episodes of overt hepatic encephalopathy falls under the programme budgeting category 13C (Problems of the Gastro Intestinal System - Hepatobiliary).

8 Summary of sensitivity analysis

8.1 A change in the proportion of people who take rifaximin with or without lactulose from year 3 onwards, from 30% to 50%, provides a range of £3.9 million to £12.6 million cost impact respectively for the population of England.

8.2 A change in the proportion of treated people currently taking rifaximin from 16% to 26% provides a range of £10.5 million and £6.1 million cost impact respectively for the population of England.

8.3 A change in the proportion of people with cirrhosis who have overt hepatic encephalopathy from 30% to 45% provides a range of £6.6 million and £9.9 million cost impact respectively for the population of England.

9 Conclusion

9.1 The resource impact from year 3 onwards is expected to be £8.2 million for the population of England. From year 3 onwards the costs are assumed to remain constant. This is based on the following standard assumptions in the model:

- After 3 years the uptake of rifaximin will be 40% of the treated population.
- Approximately 91% of people who take rifaximin take rifaximin with lactulose and the remaining 9% take rifaximin only.

9.2 Hepatic encephalopathy is a serious condition with important and far reaching effects on people with the condition and their families and carers. Expert clinical opinion suggests that rifaximin is effective in reducing the recurrence of hepatic encephalopathy episodes. Rifaximin may also reduce the length of stay in hospital, reduce hospital admissions and improve quality of life.

10 References

Fleming KM, Aithal GP, Solaymani-Dodaran M et al. (2008). Incidence and prevalence of cirrhosis in the United Kingdom, 1992-2001: a general population-based study. Journal of Hepatology 49(5):732–8

Guest J, Nanuwa K, Barden R (2014). Utility values for specific hepatic encephalopathy health states elicited from the general public in the United Kingdom. Health and quality of life outcomes 12: 89

Wolf D (2014). Hepatic Encephalopathy. Medscape (2014)