NICE National Institute for Health and Care Excellence

Resource impact summary report

Resource impact
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This summary report is based on the NICE assumptions used in the resource impact template. Users can amend the 'Inputs and eligible population' and 'Unit costs' worksheets in the template to reflect local data and assumptions.

Recommendation

NICE has recommended elafibranor, within its marketing authorisation, as an option for treating primary biliary cholangitis (PBC) in adults, when used:

- with ursodeoxycholic acid (UDCA), if the PBC has not responded well enough to UDCA, or
- alone, if UDCA cannot be tolerated.

Elafibranor is only recommended if the company provides it according to the commercial arrangement.

Eligible population for elafibranor

The following assumptions have been used to calculate the eligible population:

- UK-PBC states that PBC has a prevalence of around 35 per 100,000 people. We have calculated this to equate to a population of 19,987 in England. Evidence suggests that PBC is significantly more common in some areas.
- The British Society of Gastroenterology and UK-PBC guidelines recommend that oral UDCA is used as the first-line pharmacotherapy in all patients with PBC. But results of a UK-wide, population-based evaluation of care delivery (Abbas et al. 2023) suggest that only 87.7% of these patients have this treatment. Adherence to the guidance had regional variations.
- Forty per cent (40%) of those treated with oral UDCA first-line will have an incomplete response as per an article on the management of PBC: current treatment and future

perspectives (Bernal et al. 2023).

- The evaluation by Abbas et al. (2023) suggests that currently only 51.09% of the population who have an incomplete response to UDCA are treated with a second-line treatment. Again, there were regional differences in treatment.

Because of the regional variations in population and standard care, we encourage users to review the assumed populations and alter any assumptions that do not reflect their local circumstances in the resource impact template. Users will also need to input the market shares of the treatments in cells E57 to E61 of the 'Inputs and eligible population' worksheet.

Treatment options for the eligible population

The comparator treatment for the eligible population is OCA with or without UDCA. The resource impact template also allows users to model UDCA treatment alone, because a portion of people stop OCA treatment because of severe itching. It is assumed that people who discontinue treatment with either elafibranor or OCA have treatment with UDCA

Elafibranor and the comparators are oral treatments.

For more information about the treatments and dosing regimens, see the resource impact template.

Financial resource impact (cash items)

The company has a commercial arrangement. This makes elafibranor available to the NHS with a discount.

Users can input the confidential price of elafibranor and amend other variables in the resource impact template.

The payment mechanism for the technology is determined by the responsible commissioner and depends on the technology being classified as high cost.

For further analysis or to calculate the financial impact of cash items, see the resource impact template.

Capacity impact

For further analysis or to calculate the financial capacity impact from a commissioner (national) and provider (local) perspective, see the resource impact template.

Key information

Table 1 Key information

Time from publication to routine commissioning funding	90 days
Programme budgeting category	13C, Problems of The gastro intestinal system - HepatoBiliary
Commissioner(s)	NHS England
Provider(s)	NHS hospital trusts
Pathway position	2nd line. Recommendation states that elafibranor can be used: •in combination with UDCA, if the PBC has not responded well enough to UDCA, or •alone, if UDCA cannot be tolerated.

About this resource impact summary report

This resource impact summary report accompanies the NICE technology appraisal guidance on elafibranor for treating PBC and should be read with it.

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