NICE National Institute for Health and Care Excellence

Resource impact summary report

Resource impact

Published: 26 March 2025

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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 fenfluramine as an option for treating seizures associated with Lennox–Gastaut syndrome, as an add-on to other antiseizure medicines, for people 2 years and over. It is recommended only if:

- the frequency of drop seizures is checked every 6 months, and fenfluramine is stopped if the frequency is not reduced by at least 30% compared with the 6 months before starting treatment
- the company provides it according to the commercial arrangement.

This recommendation is not intended to affect treatment with fenfluramine that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop. For children or young people, this decision should be made jointly by the clinician, the child or young person, and their parents or carers.

Eligible population for fenfluramine

Table 1 shows the population who are eligible for fenfluramine and the number of people who are expected to have fenfluramine in each of the next 5 years, including forecast population growth.

Table 1 Population expected to be eligible for and have fenfluramine as an add-on to standard treatments in England

Eligible population and market share	Current practice (without fenfluramine)	2025 to 2026	2026 to 2027	2027 to 2028	2028 to 2029	2029 to 2030
People eligible for fenfluramine	1,490	1,500	1,520	1,535	1,550	1,565
Cumulative market share for fenfluramine (%)	0	29	37	46	47	47
People starting treatment each year	0	440	130	140	20	10
People continuing fenfluramine each year	0	0	390	470	540	510
Total people having fenfluramine each year	0	440	520	610	560	520

Note: The market shares and therefore number of people having fenfluramine treatment are cumulative. The market share is adjusted to reflect people continuing treatment from previous years and adjusts for people who stop treatment. The people continuing in subsequent years is net of discontinuations so there are fewer people continuing in future years. The rate of discontinuation applied is 10%.

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

- 70% of people who have epilepsy are diagnosed and treated for Lennox–Gastaut related seizures
- 95% of these people are treated with anti-epilepsy drugs
- Of those treated with anti-epilepsy drugs, 90% of people's condition is inadequately controlled
- 90% of people whose condition is inadequately controlled are eligible to receive fenfluramine
- 10% of people stop treatment after each year.

The market shares are based on a mid-point using company and neurology clinical expert opinion.

The market share and therefore number of people receiving each treatment are cumulative. The market share is adjusted to reflect people continuing treatment from previous years and adjusts for people who discontinue treatment. People are assumed to move to standard care once they discontinue with fenfluramine.

Treatment options for the eligible population

The comparator treatment for the eligible population is cannabidiol with clobazam plus standard care. Because fenfluramine and cannabidiol with clobazam are in addition to standard care treatments, no additional cost is assumed with standard care options.

Both fenfluramine and cannabidiol are oral solutions which can be administered at home by people or their caregivers. Clobazam has an oral tablet or oral solution formulation. The treatments are taken daily.

No additional infrastructure or resources are expected to be required to deliver this treatment. Prescribing for these treatments, drug supply and routine monitoring will be managed by tertiary care.

For more information about the treatments, such as average dose and treatment regimens, see the resource impact template.

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

Users can input the confidential price of fenfluramine 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

Table 2 shows the impact on capacity activity in each of the next 5 years. People on

fenfluramine are required to have an echocardiogram conducted every six months for the first two years and annually thereafter. This is because of reported cases of valvular heart disease that may have been caused by fenfluramine at higher doses used to treat adult obesity.

Table 2 Capacity impact (activity) in England

Capacity impact	Current practice (without fenfluramine)	2024 to 2025	2025 to 2026	2026 to 2027	2027 to 2028	2028 to 2029
Number of echocardiogram appointments	0	870	1,040	850	710	540

Capacity benefits

The studies showed that when compared with standard care without cannabidiol and clobazam, fenfluramine, at its recommended maintenance dose of 0.7 mg/kg/day, provided substantial, significant reductions in average drop seizure frequency (DSF). Fenfluramine also demonstrated a meaningful treatment effect as add-on therapy in people who were extensively pre-treated and are refractory/intolerant to multiple antiseizure medications. At year 1 of the open label extension trial, the median percentage reduction in DSF from baseline was 51.8% ($p<0.0001$). The committee concluded that fenfluramine as an add-on to standard care without cannabidiol and clobazam is more effective at reducing DSF than standard care without cannabidiol and clobazam alone.

Reducing DSF from baseline may be associated with a reduced need for unplanned and emergency hospitalisations and fewer outpatient visits. These benefits may also apply to people who switch from standard care to cannabidiol with clobazam; therefore, no additional benefits are assumed in the resource impact assessment.

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 3 Key information

Time from publication to routine commissioning funding	Early funding from the Innovative Medicines Fund (IMF) budget has been agreed for fenfluramine. IMF interim funding will end 90 days after positive final guidance is published at which point funding will switch to routine commissioning budgets.
Programme budgeting category	7X Neurological – other
Commissioner(s)	NHS England
Provider(s)	NHS hospital trusts – Tertiary care
Pathway position	Add on therapy to antiseizure medications

About this resource impact summary report

This resource impact summary report accompanies the NICE technology appraisal guidance on fenfluramine for treating Lennox Gastaut seizures in people aged 2 and over and should be read with it. See terms and conditions on the NICE website.

ISBN: 978-1-4731-6899-2