

Putting NICE guidance into practice

Resource impact report: Cannabidiol with clobazam for treating seizures associated with Lennox–Gastaut syndrome (TA615)

Published: December 2019

Summary

NICE has recommended [cannabidiol with clobazam](#) for treating seizures associated with Lennox–Gastaut syndrome in people aged 2 years and older. See section 1.1 for further details of the full recommendations.

We estimate that:

- 4,100 people (3,990 from prevalent population and 110 from newly diagnosed people) with seizures associated with Lennox–Gastaut syndrome are eligible for treatment with cannabidiol.
- Maximum uptake is estimated at 80% of the eligible population.
- 1,810 people (1,630 prevalent population and 180 from newly diagnosed people) will have cannabidiol in year 2024/25 as shown in table 1.

Table 1 Estimated number of people in England having cannabidiol

	2020/21	2021/22	2022/23	2023/24	2024/25
Prevalent population					
People in first year of treatment	800	1,200	600	390	200
People continuing with treatment from previous year	0	480	1,160	1,440	1,590
People not adhering to treatment	-80	-120	-60	-40	-20
People discontinuing treatment in year	-240	-400	-260	-200	-140
People continuing treatment into next year	480	1,160	1,440	1,590	1,630
Newly diagnosed population					
People in first year of treatment	20	60	70	80	80
People continuing with treatment from previous year	0	13	50	88	137
People not adhering to treatment	-2	-3	-2	-1	-1
People discontinuing treatment in year	-5	-20	-30	-30	-40
People continuing treatment into next year	13	50	88	137	176
Total prevalent and new cases	493	1,210	1,528	1,727	1,806

This report is supported by a local resource impact template because the list price of cannabidiol has a discount that is commercial in confidence. The discounted price of cannabidiol can be put into the template and other

variables may be amended. The list price of cannabidiol has been agreed with the Department of Health and Social Care but is considered confidential by the company until January 2020.

This technology is commissioned by NHS England. Providers are NHS hospital trusts.

1 Cannabidiol with clobazam

- 1.1 NICE has recommended [cannabidiol with clobazam](#) for treating seizures associated with Lennox–Gastaut syndrome in people aged 2 years and older only if:
- the frequency of drop seizures is checked every 6 months and cannabidiol is stopped if the frequency has not fallen by at least 30% compared with the 6 months before starting treatment
 - the company provides cannabidiol according to the commercial arrangement.
- 1.2 There are a broad range of available anti-epileptic drugs, non-pharmacological interventions (such as vagus nerve stimulation and a ketogenic diet) and surgery currently available for this population. However, clinical, and patient and carer experts suggest that these current treatments often do not control seizures associated with Lennox–Gastaut syndrome.
- 1.3 The committee concluded that there is an unmet need for treatments that reduce the number of drop seizures, and that patients and their carers would value a new treatment option.
- 1.4 Implementing the guidance may reduce seizure frequency compared with usual care and help save costs from reduced outpatient visits and hospitalisations resulting from a fall in seizure frequencies.

2 Resource impact of the guidance

- 2.1 We estimate that:
- 4,100 people (3,990 from prevalent population and 110 from incident population) with seizures associated with Lennox–Gastaut syndrome are eligible for treatment with cannabidiol.
 - Maximum uptake is estimated at 80% of the eligible population.

Resource impact report: Cannabidiol with clobazam for treating seizures associated with Lennox–Gastaut syndrome, (December 2019)

- 1,810 people (1,630 prevalent population and 180 from the newly diagnosed population) will have cannabidiol in year 2024/25 as shown in table 2.

2.2 The current treatment and future uptake figure assumptions are based on the company submission and are shown in the resource impact template. Table 2 shows the number of people in England who are estimated to have cannabidiol by financial year.

Table 2 Estimated number of people having cannabidiol using NICE assumptions

	2020/21	2021/22	2022/23	2023/24	2024/25
Prevalent population					
People in first year of treatment	800	1,200	600	390	200
People continuing with treatment from previous year	0	480	1,160	1,440	1,590
People not adhering to treatment	-80	-120	-60	-40	-20
People discontinuing treatment in year	-240	-400	-260	-200	-140
People continuing treatment into next year	480	1,160	1,440	1,590	1,630
Newly diagnosed population					
People in first year of treatment	20	60	70	80	80
People continuing with treatment from previous year	0	13	50	88	137
People not adhering to treatment	-2	-3	-2	-1	-1
People discontinuing treatment in year	-5	-20	-30	-30	-40
People continuing treatment into next year	13	50	88	137	176
Total prevalent and new cases	493	1,210	1,528	1,727	1,806

2.3 This report is supported by a local resource impact template. The list price of cannabidiol has been agreed with the Department of Health and Social Care but is considered confidential by the company until January 2020. The company has a commercial arrangement (simple discount patient access scheme). This makes cannabidiol available to the NHS with a discount. The size of the Resource impact report: Cannabidiol with clobazam for treating seizures associated with Lennox–Gastaut syndrome, (December 2019)

discount is commercial in confidence until January 2020. It is the company's responsibility to let relevant NHS organisations know details of the discount. For enquiries about the patient access scheme: RHolland@gwpharm.com or gwyatt@gwpharm.com.

Savings and benefits

- 2.4 The committee concluded that cannabidiol with clobazam reduces seizure frequency compared with usual care, but that the long-term efficacy after 3 years is uncertain. The model includes savings from reduced outpatients' visits and hospitalisations resulting from a fall in seizure frequencies.
- 2.5 Some people receiving cannabidiol may also benefit from a reduction in the dose of concomitant anti-epileptic drugs.

3 Implications for commissioners

- 3.1 This technology is commissioned by NHS England. Providers are NHS hospital trusts.
- 3.2 Cannabidiol will be incorporated into existing epilepsy care pathways and is not expected to require any additional infrastructure for its use to be implemented in the NHS.
- 3.3 Cannabidiol falls within the programme budgeting category PBC07X: Neurological.

4 How we estimated the resource impact

The population

- 4.1 Tables 3 shows the number of people from the prevalent and the newly diagnosed population who have Lennox–Gastaut syndrome, and the number of people eligible for treatment with cannabidiol.
- 4.2 The guidance recommends cannabidiol with clobazam for treating seizures associated with Lennox–Gastaut syndrome in people

Resource impact report: Cannabidiol with clobazam for treating seizures associated with Lennox–Gastaut syndrome, (December 2019)

aged 2 years and older. The model uses the population of people from 2 years up to 55 years old because of the data available and the fact that there are very few people aged 56 and over with Lennox–Gastaut syndrome.

Table 3 Number of people eligible for treatment in England

Population	Proportion (%)	Prevalent population			New cases	
		Total population	People aged 2-17 years ^a	People aged 18-55 years ^a	People 2-12 years old	Total prevalent/new cases
Population of England^a		55,619,430	10,538,683	28,005,227	7,503,644	
Prevalence of Lennox–Gastaut Syndrome ^b	0.023		2,420	n/a	n/a	
Prevalence of Lennox–Gastaut Syndrome ^b	0.018		n/a	4,990	n/a	
Incidence of Lennox–Gastaut Syndrome ^c	0.002		n/a	n/a	150	
People (new cases) diagnosed and treated for Lennox–Gastaut Syndrome ^d (A)	100		n/a	n/a	150	
People (prevalent) diagnosed and treated for Lennox–Gastaut Syndrome ^e - (B)	70		1,690	3,500	n/a	
People treated with anti-epileptic drugs ^e (A) & (B) x 95% = (C)	95		1,610	3,320	142	5,072
People with seizures inadequately controlled by anti-epileptic drugs ^e (C) x 90% = (D)	90		1,450	2,990	128	4,568
Number of people inadequately controlled with anti-epilepsy drugs who can tolerate clobazam and who are eligible for treatment (D) x 90% = (E)	90		1,300	2,690	115	4,105

a [Office of national statistics](#)

b The average of prevalence data obtained from the following 2 sources was used: Trevathan E, et al. Prevalence and descriptive epidemiology of Lennox-Gastaut syndrome among Atlanta children, *Epilepsia*, vol. 38, no. 12, pp. 1283-1288, 1997, (prevalence rate of 0.26/1000 at age of 10 years) and 0.02% from link: https://www.ema.europa.eu/en/documents/other/relevant-sources-orphan-disease-prevalence-data_en.pdf

c Heiskala H. Community-Based Study of Lennox-Gastaut Syndrome. *Epilepsia*. 1997;38:526-53.

d Autry AR, Trevathan E et al. Increased Risk of Death Among Children With Lennox-Gastaut Syndrome and Infantile Spasms. *Journal of child neurology*, 2010, 25(4) 441-447. Survival rate is estimated at 99.81%.

e Expert opinion as per company submission.

Assumptions

4.3 The resource impact template assumes that:

- Cannabidiol is taken adjunctively alongside current clinical management. Therefore, current clinical management costs are excluded from the model.
- A 90% adherence rate is assumed each year for people starting cannabidiol treatment. No data are available to provide different estimates for each age group considered.
- Cannabidiol treatment cost is based on a full year. Treatment duration is in line with the guidance recommendation. See section 4.4 for further information.
- Around 32% of people treated with cannabidiol do not achieve a threshold of a $\geq 30\%$ reduction in drop seizure frequency after 6 months of therapy therefore stop cannabidiol as a result. At 12 months and 24 months of therapy, 5% and 2% % of people treated with cannabidiol do not achieve a threshold of a $\geq 30\%$ reduction in drop seizure frequency respectively therefore stop cannabidiol as a result.
- 2.7% of people starting and continuing with treatment from previous years discontinue each year because of adverse effects or non-persistence.
- Cannabidiol will be prescribed by specialist clinicians and will be mainly administered at home by patients. Where cannabidiol is prescribed in secondary care the template can be amended to include VAT. Where a home care service is available there would be an administration charge included in the treatment cost.
- Cannabidiol is not expected to require any additional infrastructure for its use to be implemented in the NHS.
- Maximum uptake is 80% of the eligible population.

Other factors

- 4.4 The guidance recommends checking the drop in seizure frequency every 6 months and to stop cannabidiol if the frequency has not fallen by at least 30% compared with the 6 months before starting treatment. The model estimates discontinuations at 6, 12 and 24 months of therapy.
- 4.5 There are no data showing how many people achieve the threshold at 18 months after starting treatment therefore the model excludes these people. However, the number is not expected to be significant.

About this resource impact report

This resource impact report accompanies the NICE guidance on [cannabidiol with clobazam for treating seizures associated with Lennox–Gastaut syndrome](#) and should be read with it.

© NICE 2019. All rights reserved. See [Notice of rights](#).