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Welsh Health Specialised
Services Committee (WHSSC)

Specialised Services Policy Position PP203

**Cannabidiol with clobazam for treating seizures
associated with Dravet syndrome or Lennox-
Gastaut syndrome in people aged 2 years and
older.**

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Policy Statement

Welsh Health Specialised Services Committee (WHSSC) commission cannabidiol with clobazam for treating seizures associated with Dravet syndrome or Lennox–Gastaut syndrome in people aged 2 years and older in accordance with the criteria outlined in this document.

In creating this document WHSSC has reviewed all relevant guidance issued by NICE, including Technology Appraisal (TA) Guidance on Cannabidiol with clobazam for treating seizures associated with Dravet Syndrome (TA614)¹ and Cannabidiol with clobazam for treating seizures associated with Lennox-Gastaut syndrome (TA615)². We have concluded that Cannabidiol with clobazam should be made available to people with Dravet Syndrome and Lennox-Gastaut Syndrome.

Disclaimer

WHSSC assumes that healthcare professionals will use their clinical judgment, knowledge and expertise when deciding whether it is appropriate to apply this policy position statement.

This policy may not be clinically appropriate for use in all situations and does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

WHSSC disclaims any responsibility for damages arising out of the use or non-use of this policy position statement.

¹ [Overview | Cannabidiol with clobazam for treating seizures associated with Dravet syndrome | Guidance | NICE](#)

² [Overview | Cannabidiol with clobazam for treating seizures associated with Lennox–Gastaut syndrome | Guidance | NICE](#)

1. Introduction

This Policy Position Statement has been developed for the planning and delivery of cannabidiol with clobazam for treating seizures associated with Dravet syndrome or Lennox–Gastaut syndrome in people aged 2 years and older resident in Wales. This service will only be commissioned by the Welsh Health Specialised Services Committee (WHSSC) and applies to residents of all seven Health Boards in Wales.

On the 11th October 2018 the UK Government published the Misuse of Drugs (Amendments) (Cannabis and License Fees) (England, Wales and Scotland) Regulations 2018³, which amended the Misuse of Drugs Regulations 2001 to reschedule certain cannabis-based products for medicinal use with the exception of certain cannabinoids.

The review recommended that the whole class of cannabis-based products for medicinal use and all cannabis-derived medicinal products of the appropriate standard for use in humans be moved out of Schedule 1 of the Misuse of Drugs Regulations 2001 into Schedule 2⁴. This will mean those cannabis-based products can be medically prescribed, where there is unmet clinical need. The 2018 amendment regulations came into force on 1st November 2018.^{5 6}

A subsequent circular 001/2020: Epidyolex scheduling⁷ was issued by the UK Government and came into force on 24 June 2020. It draws attention to the content of the Statutory Instrument (SI) 2020 No. 559. The new provisions, The Misuse of Drugs (Amendment) (England, Wales and Scotland) Regulations 2020 amend the Misuse of Drugs Regulations 2001.

The SI places the cannabis-based medicine, 'Epidyolex', in Schedule 5 to the Misuse of Drugs Regulations 2001 ('the 2001 Regulations') with the lowest level of restrictions, with the effect that it is excepted from the prohibition on importation, exportation and possession under the Misuse of Drugs Act 1971 ('the 1971 Act').

1.1 Plain language summary

Epilepsy

Epilepsy is a common condition that affects the brain and causes seizures, which are bursts of electrical activity in the brain which have a range of

³ [The Misuse of Drugs \(Amendments\) \(Cannabis and Licence Fees\) \(England, Wales and Scotland\) Regulations 2018](#)

⁴ [Misuse of Drugs Act 1971](#)

⁵ <https://gov.wales/sites/default/files/publications/2019-06/the-rescheduling-of-cannabis-for-medicinal-purposes.pdf>

⁶ <https://gov.wales/sites/default/files/publications/2019-06/the-rescheduling-of-cannabis-for-medicinal-purposes.pdf>

⁷ [Circular 001/2020: Epidyolex scheduling, \(SI\) 2020 No. 559 - GOV.UK](#)

symptoms and affects how the brain works.⁸ In epilepsy certain signs and symptoms added together would suggest that the child has a particular medical condition known as a syndrome and this is dependent on the child's age at which seizures begin, the type of seizure, frequency and whether they are male or female and have learning difficulties.

It is well known that cannabis based medicinal products can provide therapeutic and medicinal benefits for children aged 2 years and older with particular types of epilepsy.

Dravet syndrome

Dravet syndrome is a rare, catastrophic, lifelong form of epilepsy that begins in the first year of life with frequent and/or prolonged seizures.⁹ It is possibly more common than once first thought and can cause developmental delays and learning difficulties.

The epilepsy can be mistaken for febrile convulsions in the early stages. It is not until the second year of life that more typical Dravet syndrome features become more obvious.

Lennox Gastaut syndrome

Lennox Gastaut syndrome is a condition that can occur in children and young people from 2 years of age. Although it has been known to start as young as 18 months or even as late as 7 years of age.¹⁰ It results in the child or young person having reduced intellectual ability, learning difficulties, attention deficit and delayed speech and language skills.

The child or young person may experience spasms in the first year. Later developing into multiple seizure types including seizures from sleep (tonic) or drop seizure (atonic) called because the child or young person will always “drop” to the floor. These are the most common seizures affecting this syndrome but the child or young person can be affected by a number of less common seizure types and these will be diagnosed following an abnormal EEG.¹¹

1.2 Aims and Objectives

This Policy Position Statement aims to define the commissioning position of WHSSC on the use of cannabidiol with clobazam for treating seizures associated with Dravet syndrome or Lennox–Gastaut syndrome in people aged 2 years and older in accordance with the criteria outlined in this document.

⁸ [Epilepsy - NHS](#)

⁹ [What is Dravet Syndrome?](#)

¹⁰ [Lennox-Gastaut syndrome | Epilepsy Action](#)

¹¹ [Lennox-Gastaut syndrome | Epilepsy Action](#)

The objectives of this policy are to:

- ensure commissioning for the use cannabidiol with clobazam for medicinal use is evidence based
- ensure equitable access to cannabidiol with clobazam for medicinal use
- define criteria for people with seizures associated with Dravet Syndrome and Lennox-Gastaut Syndrome and to access treatment
- improve outcomes for people with Dravet Syndrome and Lennox-Gastaut Syndrome

1.3 Epidemiology

Dravet Syndrome was previously known as Severe Myoclonic Epilepsy of Infancy (SMEI), it affects 1:15,700 individuals, 80% of whom have a mutation in their SCN1A gene. Out of 500 children with epilepsy, 2 or possibly 3 children are likely to have this form of epilepsy.¹²

Lennox–Gastaut syndrome is a severe, lifelong and treatment-resistant genetic form of epilepsy that begins in early childhood, usually between 2 years and 7 years. It is characterised by frequent seizures of different types. Lennox-Gastaut Syndrome occurs in between 1 and 5 in every 100 children with epilepsy¹³.

1.4 Current Treatment

The most common treatment used to treat epilepsy in UK clinical practice is the use of anti-epileptic drugs, (AEDs) to suppress seizures. According to NICE clinical guideline for Epilepsies, diagnosis and management (CG137)¹⁴, the AED treatment strategy should be individualised according to the epilepsy syndrome, seizure type, co-medication, co-morbidity, the person’s lifestyle, and the preferences of the person and their family and/or carers. Children with either Dravet syndrome or Lennox-Gastaut syndrome should have specialist input into their management.

Current treatment options for treating children with seizures associated with and Dravet Syndrome and Lennox-Gastaut Syndrome includes the use of AEDs, however if seizures cannot be controlled well enough after trying two or more AEDs, patients can be treated with a cannabis based medicinal product. Non-pharmacological treatment options include a ketogenic diet, vagus nerve stimulation and various other surgical procedures

The decision to start cannabidiol should be discussed with a tertiary paediatric epilepsy specialist within a specialised neurosciences centre.

¹² [Dravet syndrome | Epilepsy Action](#)

¹³ <https://www.nice.org.uk/guidance/ta615>

¹⁴ [Overview | Epilepsies: diagnosis and management | Guidance | NICE](#)

Clinical trials show that cannabidiol reduces the number of convulsive and non-convulsive seizures when compared with usual care¹⁵.

1.5 What NHS Wales has decided

WHSSC has carefully reviewed all relevant guidance issued by NICE, including the Technology Appraisal Guidance on Cannabidiol with clobazam for treating seizures associated with Dravet Syndrome (TA614)¹⁶ and Cannabidiol with clobazam for treating seizures associated with Lennox-Gastaut syndrome (TA615)¹⁷. We have concluded that cannabidiol with clobazam should be made available to children aged 2 years and older with Dravet Syndrome and Lennox-Gastaut Syndrome within the criteria set out in section 2.1.

¹⁵ [1 Recommendations | Cannabidiol with clobazam for treating seizures associated with Dravet syndrome | Guidance | NICE](#)

¹⁶ [Overview | Cannabidiol with clobazam for treating seizures associated with Dravet syndrome | Guidance | NICE](#)

¹⁷ [Overview | Cannabidiol with clobazam for treating seizures associated with Lennox–Gastaut syndrome | Guidance | NICE](#)

2. Criteria for Commissioning

The Welsh Health Specialised Services Committee approve the funding of Cannabidiol with clobazam for people aged 2 years and older with Dravet syndrome and Lennox-Gastaut Syndrome in-line with the criteria identified in the policy.

WHSSC only has commissioning responsibility for specialist tertiary paediatric services (i.e. ages 0-17). Adult epilepsy services are funded and commissioned by the patients' Local Health Board.

Suitable transition arrangements need to be in place for those children continuing their treatment in to the adult neurology service following their 18th birthday.

2.1 Inclusion Criteria

Cannabidiol with clobazam for treating seizures associated with Dravet syndrome¹⁸

Cannabidiol with clobazam is recommended as an option for treating seizures associated with Dravet syndrome in people aged 2 years and older, only if:

- the frequency of convulsive 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 arrangement¹⁹

Cannabidiol with clobazam for treating seizures associated with Lennox–Gastaut syndrome²⁰

Cannabidiol with clobazam is recommended as an option 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

¹⁸ [Overview | Cannabidiol with clobazam for treating seizures associated with Dravet syndrome | Guidance | NICE](#)

¹⁹ There is a simple discount patient access scheme for cannabidiol. Contact medinfo@gwpharm.com for details.

²⁰ [Overview | Cannabidiol with clobazam for treating seizures associated with Lennox–Gastaut syndrome | Guidance | NICE](#)

- the company provides cannabidiol according to the commercial arrangement²¹.

2.2 Exclusion Criteria

Patients need to meet the criteria set out in section 2.1

2.3 Continuation of Treatment

Healthcare professionals are expected to review a patient's health at regular intervals to ensure they are demonstrating an improvement to their health due to the treatment being given.

If no improvement to a patient's health has been recorded then clinical judgement on the continuation of treatment must be made by the treating healthcare professional.

2.4 Acceptance Criteria

WHSSC only has commissioning responsibility for specialist tertiary paediatric services (i.e. ages 0-17). Adult epilepsy services are funded and commissioned by the patients' Local Health Board.

The service outlined in this specification is for patients ordinarily resident in Wales, or otherwise the commissioning responsibility of the NHS in Wales. This excludes patients who whilst resident in Wales, are registered with a GP practice in England, but includes patients resident in England who are registered with a GP Practice in Wales.

2.5 Patient Pathway (Annex i)

The diagnosis of epilepsy in children aged 2 years and older is undertaken by an experienced Medical Practitioner with training and expertise in epilepsy. Children are referred to a Consultant Paediatric Neurologist based in lead or specialist tertiary centre.

A number of investigations and assessments are undertaken to understand the seizure type and epilepsy syndrome. It may be necessary for patients to have an electroencephalogram (EEG).

Children aged 2 years and older should receive this treatment in a child-centred environment.

Long-term video or ambulatory EEG may be used in the assessment of children who present diagnostic difficulties after clinical assessment of a standard EEG.²²

²¹ There is a simple discount patient access scheme for cannabidiol. Contact medinfo@gwpharm.com for details.

²² [1 Guidance | Epilepsies: diagnosis and management | Guidance | NICE](#)

Other investigations include Neuroimaging, Neuropsychological assessment and biochemistry tests to support with the diagnosis of the condition.

Epileptic seizures and epilepsy syndromes in children should be classified using a multi-axial diagnostic scheme. The axes that should be considered are: description of seizure and seizure type; syndrome and the cause or origin of the disease.

Patients should be referred for assessment of eligibility for treatment to Paediatric Neurologists at the following centres:

South Wales

- Children’s Hospital of Wales
University Hospital of Wales
Cardiff
- Morriston Hospital
Swansea Bay University Health Board
Swansea

North Wales

- Alder Hey Children’s Hospital
Liverpool

2.6 Exceptions

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If the patient wishes to be referred to a provider outside of the agreed pathway, and IPFR should be submitted.

Further information on making IPFR requests can be found at: [Welsh Health Specialised Services Committee \(WHSSC\) | Individual Patient Funding Requests](#)

2.7 Clinical Outcome and Quality Measures

The Provider must work to written quality standards and provide monitoring information to the lead commissioner. There are nine quality standards

listed in the NICE guidance, Epilepsy in Children and Young people, QS27²³. All centres would be expected to meet these standards²⁴.

The centre must enable the patient's, carer's and advocate's informed participation and to be able to demonstrate this. Provision should be made for patients with communication difficulties and for children, teenagers and young people.

2.8 Responsibilities

Referrers should:

- inform the patient that this treatment is not routinely funded outside the criteria in this policy, and
- refer via the agreed pathway.

Clinician considering treatment should:

- discuss all the alternative treatment with the patient;
- advise the patient of any side effects and risks of the potential treatment
- inform the patient that treatment is not routinely funded outside of the criteria in the policy, and
- confirm that there is contractual agreement with WHSSC for the treatment.

In all other circumstances an IPFR must be submitted.

²³[List of quality statements | Epilepsy in children and young people | Quality standards | NICE](#)

²⁴[Overview | Epilepsy in children and young people | Quality standards | NICE](#)

3. Documents which have informed this policy

The following documents have been used to inform this policy:

- **National Institute of Health and Care Excellence (NICE) guidance**
 - Cannabis Based medicinal products, NICE guideline [NG144] November 2019 <https://www.nice.org.uk/guidance/ng144>)
 - Cannabidiol with clobazam for treating seizures associated with Dravet syndrome Technology appraisal guidance [TA614] 18 December 2019 <https://www.nice.org.uk/guidance/ta614>
 - Cannabidiol with clobazam for treating seizures associated with Lennox–Gastaut syndrome, Technology appraisal guidance [TA615] Published date: 18 December 2019, <https://www.nice.org.uk/guidance/ta615>
 - Epilepsies: diagnosis and management Clinical guideline [CG137] Published date: January 2012 Last updated: February 2020, <https://www.nice.org.uk/guidance/cg137/chapter/>
 - Epilepsy in Children and Young People, NICE guidance (QS27) Published in February 2013 <https://www.nice.org.uk/guidance/qs27>
- **NHS England policies**
 - Letter and guidance on cannabis based products for medicinal use, Gateway Publications clearance: 08539, 31st October 2019, <https://www.england.nhs.uk/wp-content/uploads/2018/10/letter-guidance-on-cannabis-based-products-for-medicinal-use..pdf>
- **Other published documents**
 - Misuse of Drugs Act 1971 and 2001 <https://www.legislation.gov.uk/>

This document should be read in conjunction with the following documents:

- **NHS Wales**
 - All Wales Policy: [Making Decisions in Individual Patient Funding requests](#) (IPFR).
 - The Rescheduling of Cannabis for Medicinal Purposes, Published on 30th October 2018, WHC/2018/039 <https://gov.wales/sites/default/files/publications/2019-06/the-rescheduling-of-cannabis-for-medicinal-purposes.pdf>

4. Date of Review

This document will be reviewed when information is received which indicates that the policy requires revision.

5. Putting Things Right

5.1 Raising a Concern

Whilst every effort has been made to ensure that decisions made under this policy are robust and appropriate for the patient group, it is acknowledged that there may be occasions when the patient or their representative are not happy with decisions made or the treatment provided.

The patient or their representative should be guided by the clinician, or the member of NHS staff with whom the concern is raised, to the appropriate arrangements for management of their concern.

If a patient or their representative is unhappy with the care provided during the treatment or the clinical decision to withdraw treatment provided under this policy, the patient and/or their representative should be guided to the LHB for [NHS Putting Things Right](#). For services provided outside NHS Wales the patient or their representative should be guided to the [NHS Trust Concerns Procedure](#), with a copy of the concern being sent to WHSSC.

5.2 Individual Patient Funding Request (IPFR)

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If an IPFR is declined by the Panel, a patient and/or their NHS clinician has the right to request information about how the decision was reached. If the patient and their NHS clinician feel the process has not been followed in accordance with this policy, arrangements can be made for an independent review of the process to be undertaken by the patient's Local Health Board. The ground for the review, which are detailed in the All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR), must be clearly stated

If the patient wishes to be referred to a provider outside of the agreed pathway, an IPFR should be submitted.

Further information on making IPFR requests can be found at: [Welsh Health Specialised Services Committee \(WHSSC\) | Individual Patient Funding Requests](#)

6. Equality Impact and Assessment

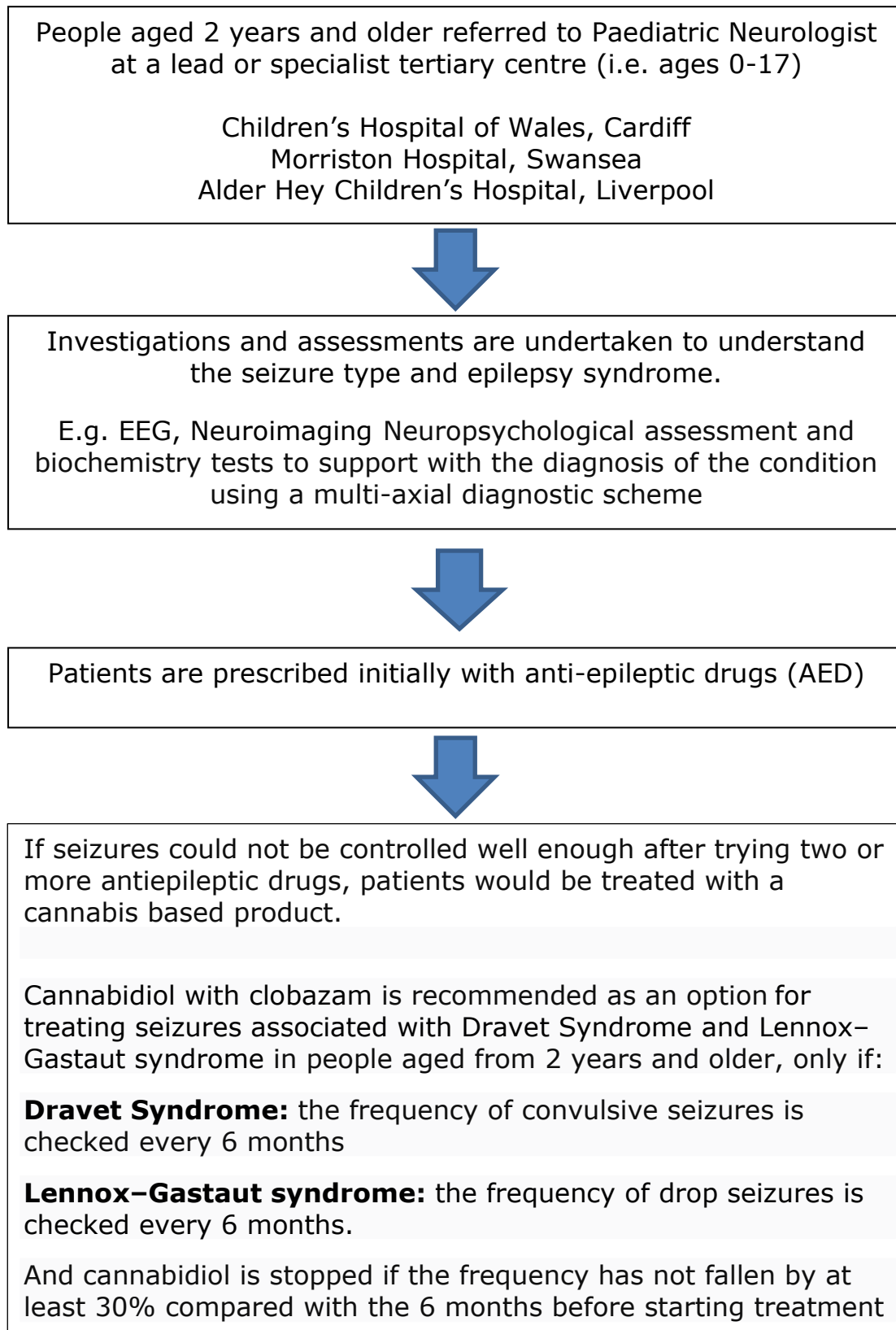
The Equality Impact Assessment (EQIA) process has been developed to help promote fair and equal treatment in the delivery of health services. It aims to enable Welsh Health Specialised Services Committee to identify and eliminate detrimental treatment caused by the adverse impact of health service policies upon groups and individuals for reasons of race, gender re-assignment, disability, sex, sexual orientation, age, religion and belief, marriage and civil partnership, pregnancy and maternity and language (Welsh).

This policy has been subjected to an Equality Impact Assessment.

The Assessment demonstrates the policy is robust and there is no potential for discrimination or adverse impact. All opportunities to promote equality have been taken.

Annex i Patient Pathway

Cannabidiol with clobazam for treating seizures associated with Dravet syndrome or Lennox–Gastaut syndrome in people aged 2 years and older (i.e. ages 0-17).



Annex ii Checklist

Cannabidiol with clobazam for treating seizures associated with Dravet syndrome or Lennox–Gastaut syndrome in people aged 2 years and older (i.e. ages 0-17).

The following checklist should be completed for every patient to whom the policy applies:

- Where the patient meet the criteria **and** the procedure is included in the contract **and** the referral is received by an agreed centre, the form should be completed and retained by the receiving centre for audit purposes.
- The patient meets the criteria **and** is received at an agreed centre, but the procedure is not included in the contract. The checklist must be completed and submitted to WHSSC for prior approval to treatment.
- The patient meets the criteria but wishes to be referred to a non-contracted provider. An Individual Patient Funding Request (IPFR) Form must be completed and submitted to WHSSC for consideration.
- If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

Annex iii Codes

Code Category	Code	Description
ICD	G40	Epilepsy and Recurrent seizures

Annex iv Abbreviations and Glossary

Abbreviations

AED	Anti-epileptic Drug
BNFC	British National Formulary for Children
EEG	Electroencephalogram
IPFR	Individual Patient Funding Request
NICE	National Institute of Health and Care Excellence
SMEI	Severe Myoclonic Epilepsy of Infancy
WHSSC	Welsh Health Specialised Services

Glossary

Anti-epileptic Drug (AED)

A medication taken daily to prevent epileptic seizures. Drug choice, suitability for syndromes and side effects will need to be cross referenced with the BNFC.

Atonic Seizure

Atonic seizures can affect both sides of the brain. Or they can be focal onset, meaning they start in just one side of the brain. Atonic seizures are sometimes called drop attacks. The muscles go all limp and the person drops to the floor. These attacks last for 1 or 2 seconds.

Dravet Syndrome

Dravet syndrome is a rare form of childhood epilepsy.

EEG

An electroencephalogram is a test used to evaluate the electrical activity in the brain.

Epilepsy

Epilepsy is a common condition that affects the brain and causes seizures, which are bursts of electrical activity in the brain which have a range of symptoms and affects how the brain works.

Epilepsy syndrome

A distinctive disorder identifiable on the basis of a typical age of onset, seizure types, specific EEG characteristics, and often other features. Identification of epilepsy syndrome has implications for treatment, management and prognosis.²⁵

²⁵ [Appendix G: Terms used in this guideline | Epilepsies: diagnosis and management | Guidance | NICE](#)

Individual Patient Funding Request (IPFR)

An IPFR is a request to Welsh Health Specialised Services Committee (WHSSC) to fund an intervention, device or treatment for patients that fall outside the range of services and treatments routinely provided across Wales.

Lennox-Gastaut syndrome

This epilepsy syndrome is uncommon but is the most common type of intractable (difficult to treat) childhood epilepsy.

Tonic Seizure

Tonic seizures means the seizure affects both sides of the brain from the start or they can be a focal onset seizures which starts in just one side of the brain.

Welsh Health Specialised Services Committee (WHSSC)

WHSSC is a joint committee of the seven local health boards in Wales. The purpose of WHSSC is to ensure that the population of Wales has fair and equitable access to the full range of Specialised Services and Tertiary Services. WHSSC ensures that specialised services are commissioned from providers that have the appropriate experience and expertise. They ensure that these providers are able to provide a robust, high quality and sustainable services, which are safe for patients and are cost effective for NHS Wales.