

Surrey and North West Sussex Area Prescribing Committee (APC)

Surrey (East Surrey CCG, Guildford & Waverley CCG, North West Surrey CCG, Surrey Downs CCG & Surrey Heath), Crawley CCG and Horsham & Mid-Sussex CCG

Title of paper:	Epidyolex (cannabidiol) – Lennox-Gastaut / Dravet syndrome		
Meeting date:	XXXXXXXXXX		
Agenda item:	To be completed by PCN secretary	Attachment(s):	2
Author and contributors:	Georgina Randall, Senior Pharmacy Technician, Pharmaceutical Commissioning (Hosted Service)		
Paper type	TA 614 / 615 and NG144		
For:	For recommendation		
Executive Summary:			
<p>NICE NG144 discusses cannabis-based medicinal products (CBMP) and their therapeutic uses. It covers the prescribing of CBMP for people with intractable nausea and vomiting, chronic pain, spasticity and severe treatment-resistant epilepsy.</p> <p>The products covered by this guideline include:</p> <ul style="list-style-type: none"> • CBMP as set out by the UK Government in The Misuse of Drugs (Amendments) (Cannabis and Licence fees) (England, Wales and Scotland) Regulations 2018. • The licensed products Sativex (THC combined with CBD) and nabilone • Plant-derived cannabinoids such as pure CBD (cannabidiol) • Synthetic compounds which are identical in structure to naturally occurring cannabinoids such as THC, for example, dronabinol <p>Epidyolex is the only pure CBD product with a marketing authorisation at this time, as follows:</p> <p>Epidyolex is indicated for use as adjunctive therapy of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS), in conjunction with clobazam, for patients 2 years of age and older.</p> <p>Subsequent to the publication of NG144, NICE has published Technology Appraisals for Epidyolex for its licensed indications of Lennox-Gastaut (TA615) and Dravet syndrome (TA614).</p>			
Please note;			
<ul style="list-style-type: none"> • The Epidyolex brand of pure CBD (cannabidiol) <u>is</u> excluded from the National Tariff for its licensed indications. • Both licensed indications are commissioned by NHS England only. • When Epidyolex is used in combination with clobazam, NHS England will routinely fund it via their Blueteq system. However, patients with Lennox-Gastaut / Dravet syndrome, but who are not using clobazam are not eligible for routine funding, and will have to apply for IFR funding from NHS England (because the indications are commissioned solely by NHS England). • Any off-indication use of Epidyolex is the responsibility of CCGs. However, Epidyolex 			

when not used for epilepsy, would not be excluded from the National Tariff, and all costs would be borne by the prescriber.

- If a product is covered by a marketing authorisation (product licence), it can be prescribed by any practitioner, such as a General Practitioner, with the authority to do so under the Misuse of Drugs Regulations 2001, even if it is for an off-label indication. This is because its quality, safety and efficacy have been established for its indicated uses.
- It is possible that GPs will be asked to continue prescribing of Epidyolex under some form of shared care agreement by a tertiary centre, (NHS England have advised that this is not their intention for the licensed indications) – primary care prescribers are advised to contact their prescribing advisor **BEFORE** agreeing to any shared care agreement or prescription arrangement, even if the patient is at risk of missing doses. **The reputational and professional risk to primary care prescribers of inadvertently writing an illegal prescription (if unlicensed) or of prescribing a dangerous dose is extremely high if advice is not sought.**
- It is likely that the CCG will receive requests to fund Epidyolex for non-licensed epilepsy syndromes via the Individual Funding Request (IFR) route; please note; cannabidiol is only excluded from the National Tariff for epilepsy indications, and not for any other indication.
- All prescribers and advisors are advised to access further information on this subject via the Health Education England (HEE) e-learning module: [Cannabis-based products for medicinal use](#)
- CBD that can be bought online or in retail outlets in the UK is not classified as a “drug” as the purity and content of these products is doubtful. If a patient says they are using these products and/or using cannabis illegally, this should be recorded in the patient’s notes for safety purposes, as CBD has known drug interactions.

Summary: *(What is the APC being asked to do and why)*

The APC is asked to consider the above information and to assign traffic light status to the following:

Epidyolex for Lennox-Gastaut / Dravet syndrome) – RED

- When used in combination with clobazam (as per NICE TA614/615) then this product is routinely commissioned by NHS England via their Blueteq system.
- When not used in combination with clobazam, but still being used for Lennox-Gastaut/Dravet syndrome, providers need to apply for funding via the NHS England IFR process.

Accompanying papers (please list):

1. NICE NG144 Cannabis-based medicinal products Published 11 November 2019
2. NICE TA614 Cannabidiol with clobazam for treating seizures associated with Dravet syndrome Published date: 18 December 2019
3. NICE TA615 Cannabidiol with clobazam for treating seizures associated with Lennox–Gastaut syndrome Published date: 18 December 2019