Briefing Paper for Surrey Heartlands Integrated Care System (ICS) Area Prescribing Committee (APC)

NICE Technology Appraisals: Local implementation

NICE TA Guidance	Cenobamate for treating focal onset seizures in epilepsy (NICE TA753)		
Available at	https://www.nice.org.uk/guidance/ta753		
Date of issue	15 December 2021 (updated 08 Feb 2022)	**Implementation deadline**	3 months from publication

Medicine details	
Name, brand name	Cenobamate (Ontozry)
Manufacturer	Arvelle Therapeutics UK
Licensed indication	Cenobamate (Ontozry, Arvelle Therapeutics) is indicated for the 'adjunctive treatment of focal onset seizures with or without secondary generalisation in adults with epilepsy who have not been adequately controlled despite treatment with at least 2 anti-epileptic medicinal products'. SPC checked 10/02/22
Formulation	Film coated tablet (SPC 10/02/22)
Usual dosage	The recommended starting dose of cenobamate is 12.5 mg per day, titrated gradually to the recommended target dose of 200 mg per day. Based on clinical response, dose may be increased to a maximum of 400 mg per day. (SPC 10/02/22)
NICE recommended dosage/schedule	As per SPC

Disease and potential patient group	
Brief description of disease	www.nhs.uk [accessed 10/02/2022] Epilepsy is a common condition that affects the brain and causes frequent seizures. Seizures are bursts of electrical activity in the brain that temporarily affect how it works. They can cause a wide range of symptoms. Epilepsy can start at any age, but usually starts either in childhood or in people over 60. It's often lifelong, but can sometimes get slowly better over time.
Potential patient numbers per 100,000	**Resource impact statement** www.nice.org.uk [accessed 10/02/2022] No significant resource impact is anticipated NICE has recommended cenobamate for treating focal onset seizures with or without secondary generalised seizures in adults with drug-resistant epilepsy that has not been adequately controlled with at least 2 antiseizure medicines. It is recommended only if: • it is used as an add-on treatment, after at least 1 other add-on treatment has not controlled seizures and • treatment is started in a tertiary epilepsy service.

	This recommendation is not intended to affect treatment with cenobamate 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. We do not expect this guidance to have a significant impact on resources; that is, the resource impact of implementing the recommendations in England will be less than £5 million per year in England (or approximately £9,000 per 100,000 population, based on a population for England of 56.3 million people). This is because cenobamate is a further treatment option; therefore, the overall cost of treatment will be similar and we do not think practice will change substantially as a result of this guidance. Short-term clinical evidence shows that cenobamate reduced the number of seizures and also increases how many people stop having any seizures. These benefits may result in capacity benefits from a reduction in administration and management costs. Cenobamate is commissioned by integrated care systems/clinical commissioning groups. Providers are NHS hospital trusts and primary care providers.

SUMMARY

NICE recommendation

1.1 Cenobamate is recommended as an option for treating focal onset seizures with or without secondary generalised seizures in adults with drug-resistant epilepsy that has not been adequately controlled with at least 2 antiseizure medicines. It is recommended only if:

- it is used as an add-on treatment, after at least 1 other add-on treatment has not controlled seizures, and
- treatment is started in a tertiary epilepsy service.

1.2 This recommendation is not intended to affect treatment with cenobamate 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.

Cost implications*

Cost of product: NHS indicative price - 28 tablets (200mg) = £182.00

Annual cost per patient: Based on max. dose of 400mg daily = £4,745 per annum

Has dose escalation been considered as part of the NICE costing template? Dose escalation is as per SPC, at time of TA publication. If product license changes over time, it is possible that further dose escalation calculations might be required.

Costing information/100,000 population and per CCG:
According to the NICE TA resource impact assessment, the CCG will be reimbursed @£9000 per 100,000 population, so for the ICS @£100,000

Availability of PAS and details (if appropriate): No

Availability of homecare service (if appropriate): No

**NICE funding requirements are based on Quality Adjusted Life Years (QALY) threshold. If there is evidence that the incremental cost rises above this threshold in the future, the APC may reconsider the commissioning status.*

Alternative treatments and cost per patient (per year / per month as appropriate)

Other NICE recommended products:
Cannabidiol (TA614/615) – RED on PAD (and not commissioned by CCG)

Options not reviewed by NICE but used in standard practice:
https://bnf.nice.org.uk/treatment-summary/epilepsy.html

Impact to patients

- It is likely that this drug will be used as a further treatment option and will form part of a long list of drugs already available for this condition. Patients suitable for this drug will already be known to the tertiary centre, and it is unlikely that any additional patients will be identified just because of this guidance.
- According to the NICE TA, cenobamate will need to be 'started' at a tertiary epilepsy service, which for our system is most likely to be St George's Hospital, Tooting.
- And unless St George's produces a shared care document which is adopted by the APC these patients will have to continue to travel to St George's for their prescriptions for the foreseeable future.

Impact to primary care prescribers

- Little to no impact to primary care until a shared care document is agreed by the APC.
- Patients that will be suitable for this drug, according to the guidance, are likely to already be already on the referral pathway to a tertiary centre.
- GPs should ensure that their patient's primary care medication record is updated to ensure that anyone accessing this record via the NHS Spine will be able to access current and accurate information on patient's medication.

Impact to secondary care

- Secondary care should only supply cenobamate if/when a patient is admitted on therapy. Some medication might need to be supplied upon discharge.
- Note; initiation should only occur in a tertiary setting.

Impact to CCGs

- It is likely that the cost of this drug is reimbursed to the CCG via a budgetary uplift as calculated by NICE when producing the TA @£9000 per 100,000 population.
- Impact to current patient pathways should be minimal as practice is unlikely to change as a result of this guidance.

Implementation

- Tertiary epilepsy centres should ensure that the drug is added to their drug formulary via the Trust DTC process(es) and that Trust pharmacies have suitable supply arrangements in place for patient access in time for the 90 day implementation deadline. SWL joint formulary process has already added these drugs to trust formularies at Croydon, St George's and Kingston hospitals (but not ESH).
- Any trust pathways will need to be amended accordingly, due attention should be paid to deprescribing and polypharmacy issues for this cohort of patients.

Recommendation to APC

PbRe: No
Recommended traffic light status (see attached guidelines):
In light of the wording in the guidance which states that the drug should be started by a tertiary epilepsy service, and because of a lack of a shared care document, the author recommends that the APC awards this drug a RED traffic light status at this time.

South West London (host commissioners for St Georges) are in discussion re implementation of this guidance. Surrey Heartlands will be guided by their decision. In the meantime in line with mandatory timescales for implementation of NICE guidance a RED traffic light status is being proposed.

Additional comments:
A cenobamate national shared care has yet to be raised as a work item at RMOC.

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Declaration of Interest:

None

Date: 10th February 2022

Reviewed by:

Name, Designation, Organisation

Declaration of Interest:

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Date: XXXX

VERSION CONTROL SHEET

Version	Date	Author	Status	Comment
v.1	*10/02/2022*	*G. Randall*	*Final*	*Accepted for March APC meeting*
v.2				
v.3				