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

INFORMATION SHEET – Blue Traffic Light Classification		
Name of medicine	Brivaracetam (Briviact®)	
Indication (including whether for adults and/or children)	Adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent patients from 16 years of age with epilepsy	
PCN policy statement reference (if applicable)	PCN 241 - 2017	
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The information sheet is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface for medicines classified by Prescribing Clinical Network as **BLUE**

BLUE drugs are considered suitable for prescribing in primary care, following initiation and stabilisation by a specialist as ongoing monitoring can be undertaken in primary care without specialist support and WITHOUT the need for a formal shared care guideline.
For each drug classified as blue, the Prescribing Clinical Network will recommend the minimum supply and whether an information sheet is required or not. A minimum of one month supply of medication will be provided by the initiating consultant.
This information sheet sets out the patient pathway relating to this medicine and any information not available in the British National Formulary and manufacturer's Summary of Product Characteristics. Prescribing must be carried out with reference to those publications. A GP or Primary Care Prescriber must ensure they are familiar with the prescribing responsibilities. This information sheet is available on the internet **http://pad.res360.net/** forming part of the Prescribing Advisory Database (PAD) giving GPs appropriate advice / guidance and is not required to be sent to the GP with the clinic letter.

RESPONSIBILITIES and ROLES

Consultant / Specialist responsibilities
1. To assess the suitability of patient for treatment, ensuring that the patient has refractory/ intractable epilepsy, and remains uncontrolled with, or are intolerant to, all other first line adjunctive anti-epileptic medicines, carbamazepine, lamotrigine, clobazam, gabapentin, levetiracetam, oxcarbazepine, sodium valproate and topiramate. Patients should not be initiated on brivaracetam unless levetiracetam has already been shown not to be effective or tolerated.
2. To discuss the aims, benefits and side effects of treatment with the patient and/or carer as well as their role
3. Explain to the patient and/or carer the treatment plan including the dosing schedule and request for transfer of care to GP.
4. Baseline monitoring undertaken, excluding patients with end-stage renal impairment and caution in patients with chronic liver disease.
5. Monitor and evaluate response to treatment, including adverse drug reactions, with the patient and to continue / discontinue treatment in line with agreed treatment plan. Patients should be monitored for signs of suicidal ideation and behaviours and appropriate treatment should be considered. Patients (and caregivers of patients) should be advised to seek medical advice should any signs of suicidal ideation or behaviour emerge.
6. Supply GP with summary of patient review demonstrating that there has been a significant reduction in seizure frequency (defined as a 50% or more reduction).
7. Advise GP when the treatment needs to be reviewed
8. Inform GP if patient does not attend planned follow-up
9. Prescribing responsibilities need to remain with the Consultant or Specialist for at least 3 months until tolerability and efficacy has been established and the dose stabilised.
10. Dose titration schedule as per Summary of Product Characteristics, and must be done by Consultant or Specialist before discharge to the GP.

General Practitioner (GP) or Primary Care Prescriber responsibilities	
1.	GP or Primary Care prescriber should only accept prescribing responsibility when they are satisfied that the treatment has been initiated in the appropriate place in therapy as described in the PCN Policy, the discharge information includes evidence of significant clinical benefit, the consultant or specialist has prescribed treatment for at least 3 months and the dose has been stabilised.
2.	Monitor patient for a small increased risk of suicidal ideation and behaviour. Seek advice from the specialist if patient is showing signs of suicidal tendencies.
3.	Check for drug interactions with any new medicines.

Patient / Carer role	
1.	Informing the specialist team, primary care prescriber or other healthcare professional if he or she has further questions or wants more information about the treatment
2.	Tell the consultant / specialist or GP or Primary Care Prescriber of any other medication being taken, including over-the-counter products.
3.	Sharing any concerns about their treatment and problems they are having taking their medicines with the specialist team, primary care prescriber or other healthcare professional involved in their care.
4.	Supported to know how to report any adverse effects to the specialist team, primary care prescriber or other healthcare professional involved in their care, and how adverse effects can be managed.
5.	To be available for monitoring as required.
6.	Attend follow-up appointments with the consultant / specialist.
7.	Seek medical advice should any signs of suicidal ideation or behaviour emerge.

Key information on the medicine

Please refer to the current edition of the British National Formulary (BNF), available at www.bnf.org, and Summary of Product Characteristics (SPC), available at www.medicines.org.uk for detailed product and prescribing information and specific guidance.

Background to disease and use of medicine for the given indication
Brivaracetam is an analogue of levetiracetam, and is licensed for the treatment of partial-onset seizures with or without secondary generalisation NICE CG137 recommends monotherapy for focal seizures wherever possible, with carbamazepine and lamotrigine considered the first-line options Adjunctive therapy is advised if monotherapy with two well-tolerated AEDs is not effective. The first line options for adjunctive treatment include carbamazepine, clobazam, gabapentin, lamotrigine, levetiracetam, oxcarbazepine, sodium valproate and topiramate. Second line options include eslicarbazepine, retigabine, lacosamide, phenobarbital, phenytoin, pregabalin, tiagabine, vigabatrin or zonisamide and brivaracetam may be considered at this stage. The PCN has not supported use of brivaracetam unless levetiracetam has been one of the agents which has been tried and failed, because they are very similar analogues and there is insufficient evidence to indicate that brivaracetam is more effective or has fewer adverse effects. Brivaracetam is much more expensive than levetiracetam and therefore should not be used in preference.

Indication
The PCN recommends Brivaracetam (Briviact®) as an adjunctive therapy in the treatment of partial-onset seizures in epileptic patients from 16 years of age.
Brivaracetam should be reserved for patients with refractory/intractable epilepsy, who remain uncontrolled with, or are intolerant to, all other adjunctive anti-epileptic medicines, carbamazepine, lamotrigine, clobazam, gabapentin, levetiracetam, oxcarbazepine, sodium valproate and topiramate, unless contra-indicated.
Patients should not be initiated on brivaracetam unless levetiracetam has already been shown not to be effective or tolerated.

Dosage and Administration
Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Expected outcome
Significant and sustained reduction in seizures

Monitoring: No monitoring recommended

Cautions, contraindications - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Adverse effects - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Drug interactions - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk