PAN MERSEY AREA PRESCRIBING COMMITTEE
PRESCRIBING POLICY STATEMENT
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NHS Pan Mersey Area Prescribing Committee

BRIVARACETAM tablets and oral solution (Briviact®▼)

AMBER

The Pan Mersey Area Prescribing Committee recommends the prescribing of BRIVARACETAM tablets/oral solution (Briviact®▼) for adjunctive treatment of focal seizures following initiation by a consultant neurologist.

FOLLOWING SPECIALIST INITIATION

AMBER patient retained by specialist in NHS Wirral CCG

The Pan Mersey Area Prescribing Committee recommends prescribing BRIVARACETAM tablets/oral solution (Briviact®▼) following consultant neurologist initiation, for adjunctive treatment of focal seizures with or without secondary generalisation in people aged 16 years and older with epilepsy.

Brivaracetam should only be prescribed following initiation by a consultant neurologist with appropriate experience in the treatment of epilepsy **when standard adjunctive therapies have failed to achieve adequate seizure control**. The Pan Mersey APC currently recommends that brivaracetam should **only** be considered when patients have received an adequate trial of levetiracetam and either failed to achieve adequate seizure control, or have been unable to continue therapy due to adverse drug effects.

Brivaracetam has not yet been reviewed by NICE. The NICE Clinical guideline 'Epilepsies: diagnosis and management' [CG137; 2012][1] recommends specific drugs for first line, adjunctive and tertiary specialist use in focal epilepsy. The recommendation for brivaracetam above would be in keeping with this existing guidance, with brivaracetam being considered on referral to tertiary care.

Please refer to the separate Pan Mersey policy statement for the use of brivaracetam in adolescents and children from 4 years of age to under 16 years of age.

Note: Patients who are not eligible for treatment under this statement may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. In this situation, follow locally defined processes.

BRIVARACETAM tablets and oral solution (Briviact®▼)

EFFECTIVENESS	SAFETY
Brivaracetam is a selective, reversible synaptic vesicle protein 2A ligand. Pooling of the data from 3 phase III studies (n = 398, n = 396, n = 764, follow-up 12 weeks, excluding patients receiving levetiracetam at the time of study entry), shows a statistically significant reduction in focal seizure frequency versus placebo[2,3,4], with seizure frequency reduced by 19.5%, 24.4% and 24.0% in the brivaracetam 25mg BD, 50mg BD and 100mg BD groups, respectively, compared to placebo.[5] Of the patients included in these phase III studies, 2.5%, 5.1% and 4.0% of patients on brivaracetam 25mg BD, 50mg BD and 100mg BD, respectively, achieved seizure freedom from all seizure types.[5]	Most adverse effects reported were mild or moderate in intensity. The most commonly reported adverse effects in clinical studies included somnolence, dizziness and fatigue.[5] Higher rates of irritability, aggression, anxiety and depression were reported in brivaracetam treated patients compared to placebo.[5] The use of anti-epileptic drugs (AEDs) in general is associated with a risk of suicidal ideation and behaviour in epilepsy patients. The incidence rate of suicidality related events observed with brivaracetam is within the range reported in community based epidemiological studies in epilepsy patients.[4] The potential for brivaracetam drug-drug interactions appears to be generally low.[5] The risks of brivaracetam in pregnancy are currently unknown and so it is not recommended to be used during pregnancy unless clinically necessary (i.e. if the benefit to the mother clearly outweighs the potential risk to the foetus).[6] For full details see the SPC.[6]
COST One year at recommended maintenance doses compared to alternatives:[7] Brivaracetam tablets £1690 (25-100mg BD) Brivaracetam oral solution £705-£2819 (25-100mg BD) Levetiracetam tablets £235-1040 (250mg-1.5g BD) Levetiracetam oral solution £41-245 (250mg-1.5g BD) Lacosamide £1128-£2255 (100-200mg BD) Tiagabine £570-£1710 (5-15mg TDS) Vigabatrin £648-£973 (1-1.5g BD) Zonisamide £216-360 (300-500mg OD)	**PATIENT FACTORS** No dose adjustment is necessary in patients with impaired renal function but brivaracetam is not recommended in patients undergoing dialysis. No dose adjustment is necessary in the elderly, but clinical experience is limited in patients ≥65 years old. Exposure to brivaracetam is increased in patients with chronic liver disease. A 25mg BD starting dose should be considered, with a maximum dose of 75mg BD in all stages of hepatic impairment.[6] No data are available on the safety and efficacy of brivaracetam in children and adolescents below the age of 16.[6]

PRESCRIBING INFORMATION

The manufacturers recommend a starting dose of 25-50mg in the morning and evening, based on physician assessment of required seizure reduction versus potential adverse effects.[6] The recommended therapeutic dose is 25-100mg BD.[6]

IMPLEMENTATION NOTES

Brivaracetam requires specialist initiation by a consultant neurologist with appropriate experience in the treatment of epilepsy. The initiating consultant will continue to prescribe brivaracetam until the initiating team has reviewed the patient and stabilisation of the patient's dose and condition has been achieved.

REFERENCES

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