

Enc 4 Appx 3

Clinical Expert Summary Brivaracetam (Briviact[®]▼) 10 mg, 25 mg, 50 mg, 75 mg, 100 mg tablets, 10 mg/ml oral solution, 10 mg/ml solution for injection/infusion

Brivaracetam (Briviact[®]▼) is indicated as adjunctive therapy in the treatment of partial-onset seizures (POS) with or without secondary generalisation in adult and adolescent patients from 16 years of age with epilepsy

1. Existing guidelines

Reference was made to NICE guidelines for the treatment of epilepsy in adults and children (2010), although these have not been updated to include brivaracetam.

2. Disease prevalence/incidence

Experts' estimates for the proportion of patients in Wales with epilepsy who would be eligible to receive brivaracetam varied. It was estimated that 30-40% of epilepsy patients do not achieve seizure control with a single first line medication, and would therefore require adjunctive therapy. However, it was also noted that other adjunctive treatments would be tried first, and in the majority of cases brivaracetam would be reserved for use in patients who have tried at least one other adjunctive therapy first.

3. Current treatment options

It was highlighted that a broad range of medicines are commonly used to treat refractory/resistant epilepsy; these include carbamazepine (Tegretol[®]), clobazam, eslicarbazepine acetate (Zebinix[®]), gabapentin, lacosamide (Vimpat[®]), lamotrigine, levetiracetam, oxcarbazepine (Trileptal[®]), perampanel (Fycompa[®]), sodium valproate, topiramate and zonisamide (Zonegran[®]). One expert stated that patients with drug refractory epilepsy, defined as a failure to respond to adequate doses of two anti-epileptic drugs (AEDs) over a 2 year period, are trialled on newer "add-on" AEDs, which could include brivaracetam.

4. Unmet needs

Experts highlighted the fact that frequent seizures can increase the risk of sudden unexplained death in epilepsy. One expert highlighted the significant morbidity (disabling seizures, neuropsychiatric complications), cognitive problems (memory, attention) and mortality (accidents) suffered by patients with drug refractory epilepsy. One expert stated that new treatments, particularly medications with novel mechanisms, were always needed for patients with resistant focal epilepsy, as some patients will have tried multiple treatments without achieving seizure control.

5. Knowledge of product in given indication

All experts stated that brivaracetam would be used as an add-on treatment in patients that were resistant to or could not tolerate existing adjunctive epilepsy treatments. Due to its availability as an IV formulation and therapeutic effectiveness from day one of administration, one expert commented that brivaracetam could benefit patients requiring the rapid addition of second AED, such as for the emergency treatment of seizures in inpatients and those in intensive therapy units. It was anticipated that any prescribing of brivaracetam would be infrequent and cautious at first, with increased prescribing only if clinical experience suggests that it is more effective than other adjunctive treatments.

It should be noted that two experts involved in compiling this response declared a personal non-specific interest, one of whom also declared a personal specific interest and non-personal, non-specific interest in relation to brivaracetam for the indication under consideration.