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Clinical Expert Summary
Lacosamide (Vimpat®) 50 mg, 100 mg, 150 mg, 200 mg film-coated tablets; 10 mg/ml syrup; 10 mg/ml solution for infusion

Lacosamide (Vimpat®) for adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in children from ≥ 4 years of age to ≤ 15 years of age with epilepsy.

1. Existing guidelines

Reference was made to the National Institute for Health and Care Excellence (NICE) guideline CG137: Epilepsies: diagnosis and management, published in 2012 and updated in 2016. One expert also commented that lacosamide was currently used only after liaising with paediatric neurologists for dosing advice.

2. Disease prevalence/incidence

The prevalence of epilepsy was estimated at one in 200 children. An expert estimated that 20–30 children in their catchment area would need a third-line medicine and could be considered for lacosamide therapy. Another expert estimated that, in their catchment area, lacosamide therapy might be considered for 100 children for whom treatment with at least one other suitable anti-epileptic medicine had failed.

In terms of new patients each year, one expert estimated 10 to 15 new prescriptions per year within their catchment area, whilst another estimated there would be approximately 50 new children each year across Wales with epilepsy refractory to first or second-line treatment, though not specifically partial-onset.

3. Current treatment options

Experts said that carbamazepine and lamotrigine are used as first-line treatments; one expert confirmed that, in line with NICE CG137, if either carbamazepine or lamotrigine were tried first and failed, then the other would be tried next. Second-line treatment options were identified as levetiracetam or topiramate. Sodium valproate was also included as a first-line treatment option by one expert and as a second-line option by another. It was stated that third-line treatments may be any anti-epileptic medicine, but with specific reference to zonisamide and lacosamide. One expert said that sodium valproate is the most commonly prescribed anti-epilepsy medicine for children. Another commented that eslicarbazepine is rarely used in children.

4. Unmet needs

The likelihood of becoming seizure-free on treatment with a first anti-epileptic medicine is 70%; this reduces to 30% with a second medicine and if this fails there is a 10% chance with each subsequent medicine. One expert said that 25–35% of children will not achieve full control of seizures. There is a small but significant chance of seizure freedom with each new drug that becomes available. Therefore, continued access to a large number of anti-epileptic medicines is important to increase the likelihood of benefit to children with intractable epilepsy, and to allow choices for both efficacy and tolerability. All anti-epileptic medicines have side effects, some of which prevent their routine use for certain patients; for example, sodium valproate in girls. It was stated that carbamazepine is less effective where secondary generalisation occurs and that traditional second-line medicines have more side effects than lacosamide. It was also mentioned that few anti-epileptic medicines are available in injectable formulations, which are needed for very ill children.

5. Knowledge of product in given indication

Experts said that paediatric neurologists or experienced paediatricians with an interest in epilepsy would use lacosamide as a third-line treatment after first- and second-line agents (carbamazepine, lamotrigine, levetiracetam, sodium valproate, topiramate) have

failed. It could also be used second-line, for example, in children for whom sodium valproate is contraindicated, and considered for emergency rescue medication care plans in children for whom intravenous phenytoin or levetiracetam were ineffective. One expert said that lacosamide is useful for children with complex neurodisability who are often on polypharmacy; and that lacosamide's lack of interactions makes it a more appealing choice of second- or third-line anticonvulsant. According to one expert, children would usually be treated with lacosamide for two years.

6. Additional comments

Lacosamide is a useful medicine for treating partial epilepsy and may work where other medicines have failed. One expert said they found it particularly helpful to treat nocturnal, frontal seizures. Experts commented that lacosamide has a good side effect profile, a very high tolerability and efficacy, it works well in combination with other medicines, and treatment failure is usually due to inefficacy rather than side effects. One expert reported that they currently use lacosamide on a named patient basis, with only drowsiness noted as a side effect. Another expert noted that the availability of a liquid formulation of lacosamide makes dose titration possible for smaller children. It was suggested that licensing lacosamide would substantially help families who currently have to travel to hospitals to get repeat prescriptions, risking deteriorating seizure control if there are gaps in treatment. One expert said that patients would probably need to have an ECG before starting lacosamide treatment.

It should be noted that no experts involved in compiling this response declared any interests in relation to lacosamide for the indication under consideration.