

## Northern (NHS) Treatment Advisory Group

### Treatment Appraisal: Decision Summary

Date	8 <sup>th</sup> June 2021
Appraisal & Details	<p><b>Perampanel (Fycompa®) for epilepsy</b></p> <p>The Northern (NHS) Treatment Advisory Group was requested to conduct an appraisal of and issue a recommendation regarding the use of perampanel for the treatment partial-onset seizures (POS) with or without secondarily generalised seizures in patients from 4 years of age and older, and primary generalised tonic-clonic (PGTC) seizures in patients from 7 years of age and older with idiopathic generalised epilepsy (IGE) in-line with the product license.</p>
Recommendation	<p><b>The NHS North East Treatment Advisory Group recommends perampanel for the treatment partial-onset seizures (POS) with or without secondarily generalised seizures in patients from 4 years of age and older, and primary generalised tonic-clonic (PGTC) seizures in patients from 7 years of age and older with idiopathic generalised epilepsy (IGE) in-line with the product license only when other treatment options recommended by NICE have been tried or fully considered.</b></p> <p>The group recommends that perampanel should only be initiated by specialists.</p> <p>This an update to the previous NTAG recommendation for perampanel from November 2012 to include the license extension in children under the age of 12 years old.</p>
Clinical evidence summary	<p>The original product license from June 2012 was for adjunctive treatment of partial-onset seizures, with or without secondarily generalised seizures, in patients with epilepsy aged 12 years and older.</p> <p>On the 10th of November 2020 a license extension was granted for partial-onset seizures (POS) with or without secondarily generalised seizures in patients from 4 years of age and older, and for primary generalised tonic-clonic (PGTC) seizures in patients from 7 years of age and older with idiopathic generalised epilepsy (IGE).</p> <p>The group acknowledged that perampanel had been evaluated in a robust clinical programme although the group was disappointed with the relatively short duration of the observation period and the absence of an active treatment comparator. The group was satisfied that perampanel could have substantial and important clinical benefits for some, but not all, patients. The group noted the high rate of adverse effects although acknowledged that this was observed in a refractory patient population with high levels of concomitant medication use and that most adverse effects were mild or moderate in severity.</p>
Safety	<p>The safety of perampanel has been evaluated primarily in the phase 3 studies. Perampanel is associated with a substantial burden of adverse effects although the patient group was also using multiple concomitant medications. Most adverse effects were mild or moderate in severity. The most common adverse effects were dizziness, somnolence, headache and fatigue.</p> <p>Based on the clinical trial database of 180 paediatric patients exposed to perampanel from a multicentre, open label study, the overall safety profile in</p>

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	<p>children was similar to that established for adolescents and adults, except for somnolence, irritability, aggression, and agitation which were observed more frequently in the paediatric studies compared to studies in adolescents and adults.</p> <p>No long term data or study outcomes to indicate the impact of taking perampanel as adjunctive therapy, on cognition and growth in the paediatric population aged between 4 and 12 years of age.</p> <p>Perampanel is not associated with any additional, onerous or exceptional monitoring requirements compared with other anti-epileptic drugs.</p>
Patient Perspective	Perampanel is another additional treatment option for patient with some forms of epilepsy when other treatment options recommended by NICE have been tried or fully considered.
Cost analysis summary	<p>The perampanel mean cost per patient per annum was estimated to be more than most other anti-epileptic drugs licensed or recommended for epilepsy. The perampanel maximum cost per patient per annum was estimated to be less than some other anti-epileptic drugs used for epilepsy</p> <p>Perampanel Tablets 2mg, 4mg, 6mg, 8mg, 10mg, or 12mg each pack containing 28 tablets. Irrespective of tablet strength, the cost of perampanel per tablet is £5 per tablet. The range of tablets available covers all licensed treatment doses. Cost of perampanel tablets 2mg to 12mg once daily = £1820 per patient per year.</p> <p>The oral liquid Perampanel is a 340ml bottle (500microgram/ml) costs £127.50. Once open the bottle has a 90 day shelf life – meaning a bottle may be a more cost effective option in children depending on their weight. The cost of treatment differs according to dose which is calculated based on the patient’s weight and age.</p> <p>2mg dose of oral liquid = £1.50 vs 2mg tablet = £5  4mg dose of oral liquid = £3 vs 4mg tablet = £5  6mg dose of oral liquid = £4.50 vs 6mg tablet = £5 (usual max maintenance dose in child up to approx. 5-6 years old)  8mg dose of oral liquid = £6 vs 8mg tablet = £5 (usual max maintenance dose in child up to approx. 10 years old)  12mg dose of oral liquid = £9 vs 12mg tablet = £5 (max dose)</p>
Financial impact PbR: Tariff included	<p>An estimate of the number of patients within NHS North East was made based on the uptake of other recent new anti-epileptic drugs. Originally after four years it was estimated that 85 patients would be treated with perampanel at an annual cost of about £155,000.</p> <p>It is approximated that within the North East region approximately 30-40 children will be prescribed Perampanel under the extended license.</p> <p>In 2020/21 at total of £492,481 was spent on all presentations of perampanel in the NE&amp;NC.</p>