LMMG New Medicine Recommendation

Oxcarbazepine (Trileptal®) for the treatment of epilepsy

LMMG Recommendation:

Amber 0: Oxcarbazepine (Trileptal®) is recommended for use as monotherapy or adjunctive therapy in partial (focal) epilepsy only when carbamazepine, lamotrigine, sodium valproate and levetiracetam are not appropriate or not tolerated.

Since NICE Clinical Guideline 137 was issued, the cost of levetiracetam has decreased to a level where, based on limited evidence, it is likely to be a more cost effective option than oxcarbazepine in partial epilepsy. Evidence of greater cost effectiveness of oxcarbazepine in other uses (e.g. generalised tonic clonic seizures, or benign epilepsy with centrotemporal spikes, Panayiotopoulos syndrome or late-onset childhood occipital epilepsy [Gastaut type]) in the context of its significantly greater acquisition costs is lacking.

Summary of supporting evidence:

- Oxcarbazepine is currently recommended in NICE CG 137 for use when initial recommended first-line AEDs (sodium valproate in generalised tonic clonic seizures, or lamotrigine and carbamazepine in other NICE recommended uses) are unsuitable or not tolerated. There are no clinical data specific to the use of oxcarbazepine in these circumstances.
- Available data suggest oxcarbazepine and carbamazepine have comparable efficacy and are equally well tolerated in the partial epilepsy setting. There is no evidence of differences in health-related quality of life.
- Evidence for off-label use of oxcarbazepine in generalised tonic clonic seizures is based largely on indirect comparisons. Robust direct comparative data are lacking.
- Evidence for off-label use of oxcarbazepine in benign epilepsy with centrotemporal spikes, Panayiotopoulos syndrome or late-onset childhood occipital epilepsy is lacking; the NICE Clinical Guideline extrapolated use in partial epilepsy to this patient group.
- The NICE Clinical Guideline Development Group adopted a pragmatic approach to determine the place in therapy of oxcarbazepine, which considered it's significantly greater acquisition costs in the absence of robust evidence of superiority versus carbamazepine and lamotrigine, and the lack of evidence of cost effectiveness versus sodium valproate. Although not reflected in the headline recommendations of NICE Clinical Guideline 137, the evidence review conducted by the Guideline Development Group suggests sodium valproate would be the next most cost effective option where lamotrigine and carbamazepine are not suitable or tolerated, with oxcarbazepine as an alternative when sodium valproate is not appropriate.
- The relative clinical and cost effectiveness of oxcarbazepine versus levetiracetam, which was recommended as a treatment option alongside oxcarbazepine in partial epilepsy, is currently unclear, but NICE noted that levetiracetam would be more cost

effective than oxcarbazepine if its price decreased from that in June 2011 by 50%. The drug tariff price of levetiracetam (a category M drug) has decreased by around 90% since June 2011 (as of August 2013).

- Acquisition costs are significantly greater for oxcarbazepine compared with alternative AEDs recommended for use in the same position by NICE.

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Version:	**LMMG Recommendation**	
Reviewer:	**Warren Linley**	
Clinical Reference Group (if appropriate)	**Neurology**	
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Date of recommendation to member organisations by LMMG:	**September 2013**	

Details of Review

Name of medicine (generic & brand name)**:** Oxcarbazepine (non-proprietary) Oxcarbazepine (Trileptal®)
Strength(s) and Form(s): Available as non-proprietary tablets 150mg, 300mg and 600mg Brand available as film-coated tablets 150mg, 300mg and 600mg and Oral Suspension: 300 mg/5 mL (60 mg/mL)
Licensed indication(s): Trileptal® is indicated for the treatment of partial seizures with or without secondarily generalised tonic-clonic seizures. Trileptal® is indicated for use as monotherapy or adjunctive therapy in adults and in children of 6 years of age and above.
Reason for Review: Identified as an AED which does not have a formulary decision against it. NICE CG137 for Epilepsy recommends oxcarbazepine as an option within its licensed indication and for off-label uses when usual first-line AEDs are unsuitable or not tolerated.
Proposed use (if different from or in addition to licensed indication above):

Background and context

Carbamazepine is a well-established antiepileptic drug (AED) that is licensed for use in generalised tonic-clonic and partial (focal) seizures [1]. Oxcarbazepine is a newer AED, structurally related to carbamazepine that is claimed to be better tolerated. It is licensed for use in the treatment of partial seizures with or without secondarily generalised tonic-clonic seizures [2]. NICE Technology Appraisal 76 from 2004 recommended oxcarbazepine and other newer AEDs, within their licensed indications, for the management of epilepsy in people who have not benefited from treatment with an older antiepileptic drug such as carbamazepine or sodium valproate, or for whom carbamazepine or sodium valproate are unsuitable [3]. This Technology Appraisal has since been updated and replaced in 2012 by NICE Clinical Guideline 137 [4], which recommends oxcarbazepine as a treatment option in the following situations:

Focal epilepsy: as a first-line AED option among levetiracetam[1]* and sodium valproate when carbamazepine or lamotrigine are unsuitable or not tolerated, or as an adjunctive AED (among carbamazepine, clobazam, gabapentin, lamotrigine, levetiracetam, sodium valproate or topiramate);

Generalised tonic-clonic seizures: as a possible first-line AED option (among lamotrigine and carbamazepine) when sodium valproate is not appropriate, but be aware that carbamazepine and oxcarbazepine may exacerbate myoclonic or absence seizures. Oxcarbazepine is not licensed for use in this patient population;

In children and young people with benign epilepsy with centrotemporal spikes, Panayiotopoulos syndrome or late-onset childhood occipital epilepsy (Gastaut type): as a first-line AED option (among levetiracetam* and sodium valproate) when carbamazepine or lamotrigine are unsuitable or not tolerated, or as an adjunctive AED (among carbamazepine, clobazam, gabapentin, lamotrigine, levetiracetam, sodium valproate or topiramate). Oxcarbazepine is not licensed for use in this patient population.

As NICE Technology Appraisal 76 has been replaced by the NICE Clinical Guideline 137, a mandatory funding direction for oxcarbazepine does not currently exist. Lack of a formulary decision for this medicine was originally identified by the New Medicines Group in 2012.

Evidence in Proposed Use

This evidence review draws largely on the comprehensive overviews of key efficacy and safety data included in a Cochrane review of oxcarbazepine versus carbamazepine in the treatment of partial (focal) epilepsy [5], and the evidence review conducted for NICE Clinical Guideline 137 [4, 7], supplemented with their primary data sources where necessary.

Summary of Efficacy for Oxcarbazepine in its Licensed Indication for Partial (Focal) Epilepsy

A 2009 Cochrane review of oxcarbazepine versus carbamazepine monotherapy in the treatment of partial epilepsy identified one trial using adequate measures of efficacy [5]. This was the Standard and New Epileptic Drugs (SANAD) trial, which was a randomised, unblinded trial conducted in outpatient clinics in the UK [6].

[1]* Levetiracetam was only recommended provided the acquisition cost of levetiracetam was at least 50% less than the June 2011 Drug Tariff listed cost (£2.74 for 1500mg daily dose). Levetiracetam is a Category M medicine with a cost in August 2013 of £0.21 for a 1500mg daily dose.

Patients: Had a history of two or more definite unprovoked epileptic seizures in the year prior to randomisation and carbamazepine was the better standard treatment option compared to valproate. 88% of patients had cryptogenic or symptomatic partial epilepsy. Patients with acute symptomatic seizures (e.g. febrile seizures), those aged fours year of age or younger or those with a history of progressive neurological disease were excluded.
Interventions and Comparators: A total of 1721 patients were randomised to either carbamazepine (378), gabapentin (377), lamotrigine (378) oxcarbazepine (210) or topiramate (378). The oxcarbazepine arm was included after the trial had commenced. Drug titration, initial maintenance dose and any increments or decrements were decided by the clinician.
Outcomes: Occurrence of seizures, adverse events and hospital admissions were documented at 3, 6 and 12 months and then yearly. There were no significant differences between oxcarbazepine and carbamazepine for overall treatment failure (withdrawal) rates (hazard ratio [HR] 1.04; 95% CI 0.78 to 1.39). The study authors noted that oxcarbazepine might be less likely than carbamazepine to fail because of adverse effects (HR 0·85; 95% CI 0.59 to 1.24), but more likely to fail because of inadequate seizure control (HR 1·33; 95% CI 0.82 to 2.15). Carbamazepine and oxcarbazepine appear broadly similar, although confidence intervals are wide and should not be taken to imply equivalence between the two drugs [5,6].

From this study, time to treatment failure for lamotrigine was statistically significantly improved compared with carbamazepine, but there was no statistically significant difference between oxcarbazepine and lamotrigine or topiramate. For time to achieve 12 month remission, carbamazepine seems to be the preferred treatment in all pair-wise comparisons but was not statistically superior to oxcarbazepine (or lamotrigine or topiramate) [6].

Other Efficacy Data

The evidence review undertaken for NICE CG 137 [7] identified a published individual patient data network meta-analysis that combines direct and indirect trial evidence for AEDs [8]. Based on 20 trials (mostly in adult patients) included among eight Cochrane reviews, relative estimates of time to treatment failure, time to 12 month remission and time to first seizure for partial onset and generalised tonic colonic seizures have been made for eight AEDs when used as monotherapy.

Partial (Focal) epilepsy:
There were no statistically significant differences observed between oxcarbazepine and carbamazepine or sodium valproate, for time to treatment failure, time to 12 month remission and time to first seizure. There was no significant difference between oxcarbazepine and lamotrigine in the time to treatment failure or time to 12 month remission; however, oxcarbazepine was reported to be significantly more effective than lamotrigine in prolonging the time to first seizure (based on indirect comparisons versus carbamazepine).

Lamotrigine statistically significantly improved time to treatment failure compared with carbamazepine (hazard ratio 0.70; 95% CI 0.58 to 0.83) and other AEDs included in the analysis (except oxcarbazepine). There was no significant difference between lamotrigine and carbamazepine for time to 12 month remission, but time to first seizure was significantly longer with carbamazepine than with lamotrigine (HR 1.29; 95% CI 1.13 to 1.48) . [7]. The authors of the analyses conclude that lamotrigine, carbamazepine and oxcarbazepine provide the best combination of seizure control and treatment failure [8]. Levetiracetam was not included in this efficacy analysis.

Evidence for use of oxcarbazepine as adjunctive treatment in partial (focal) refractory epilepsy is limited to placebo-controlled trials rated as of low / very low quality by the NICE Clinical guideline development group [7]. Oxcarbazepine adjunctive therapy significantly improved the proportion of patients achieving a 50% reduction in seizure frequency, and seizure freedom, but there was no significant difference in withdrawals due to lack of effect compared with placebo.

Generalised tonic clonic seizures:
The individual patient data network meta-analysis found no statistically significant differences between oxcarbazepine and any other AEDs, including carbamazepine and lamotrigine, for time to treatment failure, time to 12 month remission and time to first seizure when used as monotherapy for generalised tonic clinic seizures [7].

Benign epilepsy with centrotemporal spikes, Panayiotopoulos syndrome or late-onset childhood occipital epilepsy (Gastaut type):
Evidence for use oxcarbazepine monotherapy is limited to a single open-label trial against levetiracetam in patients with newly diagnosed benign epilepsy of childhood with centrotemporal spikes, which the NICE Clinical Guideline Development Group considered to provide very low quality evidence. This trial found no statistically significant differences between levetiracetam and oxcarbazepine for seizure freedom or withdrawal due to lack of efficacy [7]. Due to the limited evidence available in this patient group the NICE Guideline Development Group extrapolated the results from the focal seizures review because these epilepsies are characterised by focal seizures [7].

Summary of Safety Data:

The manufacturers' Summary of Product Characteristics list common and very common adverse effects of carbamazepine and oxcarbazepine as in Table 1. The very common effects are highlighted in bold.

The undesirable effects are ranked under frequency according to CIOMS III frequency classification: very common (≥ 1/10), common (≥ 1/100, < 1/10) and very rare (< 1/10,000).

Table1:

System	Carbamazepine [1]	Oxcarbazepine[2]
Blood & lymphatic system disorders	**Leukopenia** Thrombocytopenia Eosinophilia	
Endocrine (metabolic & nutrition) disorders	Oedema Fluid retention Weight increase Hyponatraemia Blood osmolality decreased	Hyponatraemia
Nervous system disorders	**Dizziness** **Fatigue** **Ataxia** **Drowsiness** Headache	**Dizziness** **Fatigue** **Somnolence** **Headache** Apathy Confusional state Depression Agitation Affect lability Ataxia Asthenia Tremor Disturbance in attention Amnesia
Eye disorders	Diplopia Blurred vision	**Diplopia** Blurred vision Visual disturbances

Ear & Labyrinth disorders		Vertigo
Gastro-intestinal disorders	**Nausea** **Vomiting** Dry mouth	Nausea Vomiting Diarrhoea Constipation Abdominal pain.
Hepato-biliary disorders	**Increased in gamma-GT** Increase in blood alkaline phosphatase	
Skin & subcutaneous tissue disorders	**Dermatitis, allergic** **Urticaria** *Stevens-Johnson syndrome**	Rash Alopecia Acne *Stevens-Johnson syndrome**

*very rare

The Cochrane review [5] assessed the adverse effects of oxcarbazepine versus carbamazepine based on three trials. There were no significant differences in the overall number of adverse events between the two drugs (OR 0.87, 95% CI 0.64 to 1.18) or in the occurrence of allergic rash dizziness or vertigo, or headache. There were significantly fewer occurrences of nausea or vomiting, or both, with carbamazepine treatment compared with oxcarbazepine (OR 3.15; 95% CI 1.39 to 7.14), but there were no significant differences between carbamazepine and oxcarbazepine in the time to treatment withdrawal due to unacceptable adverse events. The authors conclude the two AEDS have similar tolerability [5].

Adverse effects data identified for the NICE clinical guideline were generally of very low quality [7]. There were no statistically significant differences reported in withdrawals due to adverse events between oxcarbazepine and carbamazepine, lamotrigine, sodium valproate, or other AEDs when used as monotherapy in the treatment of partial epilepsy. Comparative safety data relative to other NICE-recommended AEDs are lacking.

Summary of Evidence on Cost Effectiveness and Patient Outcomes:
The evidence review conducted for the NICE Clinical Guideline [7] identified several published cost-effectiveness analyses of AEDs, which it noted had potentially serious limitations. Therefore, new analyses were conducted by the Guideline Development Group using data from the individual patient data meta-analysis (IPD MA) discussed above. This modelled outcomes and costs over a 15 year time horizon and permitted comparisons of a wider range of AEDs. Key conclusions of the available economic evidence are summarised below.

There were no statistically significant differences in patient-rated health status or quality of life between oxcarbazepine and carbamazepine or lamotrigine. No comparative data against sodium valproate were identified [7].

Partial (Focal) epilepsy:
Across all comparators, lamotrigine was estimated to be the most cost effective first-line monotherapy, with carbamazepine also a cost effective option based on results sensitivity analyses. Compared to carbamazepine, oxcarbazepine as a first-line AED had an incremental cost per QALY gained of that ranged widely between £6,000 (based on data form SANAD) and £127,000 (based on data from the IPD MA). Given this uncertainty in the cost effectiveness of oxcarbazepine, and the fact that acquisition costs for oxcarbazepine are significantly greater than those for either carbamazepine or lamotrigine, the Guideline Development Group recommended oxcarbazepine for use only when carbamazepine or lamotrigine are unsuitable or not tolerated. Of note, although oxcarbazepine was more effective (generated more QALYs) than sodium valproate, it was not cost effective (incremental cost per QALY gained £38,000) compared to sodium valproate. The Guideline Development Group assumed that evidence from first-line use would be applicable to second-line use, and therefore if lamotrigine was trialled and poorly tolerated and

carbamazepine was unsuitable for any given reason, sodium valproate would represent the next most cost-effective choice, with oxcarbazepine an alternative if sodium valproate was inappropriate. Levetiracetam (at its June 2011 list price) was considered as an alternative first-line treatment where none of the other first line treatments was considered appropriate; however, a reduction in the cost of levetiracetam by 50% or more would make levetiracetam more cost effective than oxcarbazepine, and an alternative to sodium valproate [7]. As of August 2013, the list price of levetiracetam (category M) is around 90% lower than it was in June 2011.

For refractory focal seizures, adjunctive therapy was more effective and more costly than continuing patients on monotherapy, and may be cost effective, but there was significant uncertainty around which AED would be the most cost effective when used as adjunctive therapy, due to individual patient factors and treatment history. Lamotrigine and oxcarbazepine, if not already tried as first-line AEDs, are recommended on the basis that they were the two AEDs with the greatest probability of being cost-effective in the base case and other scenarios [7].

Generalised tonic clonic seizures:
No economic evidence was identified or presented in the evidence review conducted for NICE CG 137 [7].

Benign epilepsy with centrotemporal spikes, Panayiotopoulos syndrome or late-onset childhood occipital epilepsy (Gastaut type):
No economic evidence on the relative cost-effectiveness of AEDs was identified for this population specifically; the Guideline Development Group considered the results of the economic modelling undertaken for the treatment of partial epilepsy to be applicable to this group of patients [7].

Key Points to Note from the Available Evidence:

- Oxcarbazepine is currently recommended in NICE CG 137 for use when initial recommended first-line AEDs (sodium valproate in generalised tonic clonic seizures, or lamotrigine and carbamazepine in other NICE recommended uses) are unsuitable or not tolerated. There are no clinical data specific to the use of oxcarbazepine in these circumstances.
- Available data suggest oxcarbazepine and carbamazepine have comparable efficacy and are equally well tolerated in the partial epilepsy setting. There is no evidence of differences in health-related quality of life.
- Evidence for off-label use of oxcarbazepine in generalised tonic clonic seizures is based largely on indirect comparisons. Robust direct comparative data are lacking.
- Evidence for off-label use of oxcarbazepine in benign epilepsy with centrotemporal spikes, Panayiotopoulos syndrome or late-onset childhood occipital epilepsy is lacking; the NICE Clinical Guideline extrapolated use in partial epilepsy to this patient group.
- The NICE Clinical Guideline Development Group adopted a pragmatic approach to determine the place in therapy of oxcarbazepine, which considered it's significantly greater acquisition costs in the absence of robust evidence of superiority versus carbamazepine and lamotrigine, and the lack of evidence of cost effectiveness versus sodium valproate. Although not reflected in the headline recommendations of NICE Clinical Guideline 137, the evidence review conducted by the Guideline Development Group suggests sodium valproate would be the next most cost effective option where lamotrigine and carbamazepine are not suitable or tolerated, with oxcarbazepine as an alternative when sodium valproate is not appropriate.
- The relative clinical and cost effectiveness of oxcarbazepine versus levetiracetam, which was recommended as a treatment option alongside oxcarbazepine in partial epilepsy, is currently unclear, but NICE noted that levetiracetam would be more cost effective than oxcarbazepine if its price decreased from that in June 2011 by 50%. The drug tariff price of levetiracetam (a category M drug) has decreased by around 90% since June 2011 (as of August 2013).

- Acquisition costs are significantly greater for oxcarbazepine compared with alternative AEDs recommended for use in the same position by NICE.

Productivity, Service Delivery and Implementation Considerations:

No productivity, service delivery or implementation impacts are anticipated.

Innovation, Need and Equity Considerations:

There is no evidence to suggest oxcarbazepine is an innovative AED. There are no anticipated issues related to equity.

Recommended Place in Therapy

Oxcarbazepine (Trileptal®) is recommended for use as monotherapy or adjunctive therapy in partial (focal) epilepsy only when carbamazepine, lamotrigine, sodium valproate and levetiracetam are not appropriate or not tolerated.

Since NICE Clinical Guideline 137 was issued, the cost of levetiracetam has decreased to a level where, based on limited evidence, it is likely to be a more cost effective option than oxcarbazepine in partial epilepsy. Evidence of greater cost effectiveness of oxcarbazepine in other uses (e.g. generalised tonic clonic seizures, or benign epilepsy with centrotemporal spikes, Panayiotopoulos syndrome or late-onset childhood occipital epilepsy [Gastaut type]) in the context of its significantly greater acquisition costs is lacking.

Financial and Service Implications

Comparative unit costs:
Table 2 includes example comparative unit costs for oxcarbazepine and other alternatives stated in NICE clinical guideline 137. As AEDs may be used as monotherapy or as adjunctive therapy, and doses need to be individually tailored to patients, this table is for illustrative purposes only. Acquisition costs for oxcarbazepine are significantly greater than for other the AEDs.

Anticipated patient numbers and net budget impact:
Based on the GP QOF register for 2011/12, there is a total population of 10,876 people over the age of 18 with an epilepsy code [9]. This cannot be differentiated into different types of epilepsy. It also does not include children. However, based on a national estimate that 1% of the population (across Lancashire there would be an estimate of 15,207 patients) will have a diagnosis of epilepsy at some time in their life. Therefore, in Lancashire there may be 4,331 children and young people also with the diagnosis.

Based on ePACT data for the period February to April 2013 [10] and extrapolating to 12 months there are 1,780 items of Oxcarbazepine prescribed in primary care in Lancashire each year, at an annual cost of £71,000. As expected, prescribing of carbamazepine is significantly greater at 71,900 items and an annual cost of £614,000. As AEDs such as carbamazepine may be prescribed for different types of epilepsy syndromes/seizure types, and or non-epilepsy-related conditions, it is difficult to determine the likely scale or impact of wider prescribing of oxcarbazepine for epilepsy but the average item cost would indicate a five-fold increase for oxcarbazepine compared with carbamazepine (different to the calculated costs on daily doses which is two-fold).

Table 2. Example annual acquisition costs of oxcarbazepine and potential comparators

Drug name	Example maintenance regimen	Annual maintenance cost per patient (ex VAT)
Oxcarbazepine (non-proprietary)	600 to 2400mg daily	£328 to £1312
Oxcarbazepine (Trileptal®)	600 to 2400mg daily	£298 to £1191
Carbamazepine MR (non-proprietary)	800 to 1200mg daily	£133 to £201
Lamotrigine (non-proprietary)	100 to 400mg daily*	£26 to £58
Levetiracetam (non-proprietary)	1,000 to 3,000mg daily	£51 to £146
Sodium valproate (Epilim®)	1,000 to 2,000mg daily	£141 to £281
Costs based on Drug Tariff list prices (or MIMS list prices for Trileptal® and Epilim®) as of August 2013 *Dose influenced by concomitant enzyme inducers This table does not imply therapeutic equivalence of drugs or doses.		

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