



Cost effectiveness of Pregabalin (Lyrica®) for the treatment of patients with neuropathic pain

The NCPE has issued a recommendation regarding the cost effectiveness of pregabalin (Lyrica®) for the treatment of patients with neuropathic pain. The NCPE does not recommend reimbursement of pregabalin (Lyrica®) on the community drugs scheme.

The HSE MMP has asked the National Centre for Pharmacoeconomics (NCPE) to carry out an assessment of the cost effectiveness of pregabalin (Lyrica®) for the treatment of patients with neuropathic pain and generalised anxiety disorder. The NCPE uses a decision framework to systematically assess whether a technology is cost effective. This includes clinical effectiveness and health related quality of life benefits, which the new treatment may provide and whether the cost requested by the pharmaceutical company is justified.

Following the recommendation from the NCPE, the HSE examine all the evidence which may be relevant for the decision; the final decision on reimbursement is made by the HSE. In the case of cancer drugs, the NCPE recommendation is also considered by the National Cancer Control Programme (NCCP) Technology Review Group.

About the National Centre for Pharmacoeconomics

The NCPE are a team of clinicians, pharmacists, pharmacologists and statisticians who evaluate the benefit and costs of medical technologies and provide advice to the HSE. We also obtain valuable support from clinicians with expertise in the specific clinical area under consideration. Our aim is to provide impartial advice to help decision makers provide the most effective, safe and value for money treatments for patients. Our advice is for consideration by anyone who has a responsibility for commissioning or providing healthcare, public health or social care services.

1. In June 2013 the Medicines Management Programme requested that the National Centre for Pharmacoeconomics review the cost-effectiveness analysis of pregabalin (Lyrica®) for the healthcare payer. In September 2013 the manufacturer Pfizer submitted a cost-effectiveness analysis for pregabalin for the treatment of patients with treatment-refractory neuropathic pain. Cost effectiveness for generalised anxiety disorder was not submitted at this time.
2. A cost utility analysis was submitted from the perspective of the healthcare payer. The stated objective of the pharmacoeconomic submission was to determine the cost effectiveness of pregabalin in combination with usual care as compared to usual care alone, on the GMS scheme for the management of patients with treatment refractory neuropathic pain. This subgroup was chosen in line with market research performed by Pfizer. The NCPE analysis of the Primary Care Reimbursement Service (PCRS) database indicated that the majority of patients had not received prior treatment with neuropathic pain treatments.
3. Usual care was defined as treatment with one or more weak opioids, strong opioids, NSAIDs or analgesics. It appears that treatments such as gabapentin, duloxetine, carbamazepine or venlafaxine were not included in the usual care arm.
4. Randomised controlled trials (RCTs) were not included in the dossier as the company highlight that there are no RCTs for pregabalin specific to treatment refractory pain. Four studies were presented to support the beneficial effect of pregabalin in treatment refractory pain. The review group considered that the data presented was subject to significant limitations including small sample size, uncontrolled trials and short duration. The data were not formally combined to produce an estimate of effect.
5. The TreeAge® model used a 1 week cycle length and a 10 year time horizon. The model includes three health states at different pain intensities (0 to <4=mild/no pain, ≥4 to <7=moderate pain and ≥7 to 10=severe pain). The

longest trial data provided was 15 months; the average pain score is extrapolated out to 10 years using LOCF method. The uncertainty around this has not been explored in the submission.

6. Utilities were mapped to pain scores using data collected from a survey of patients in the UK. The study included patients with refractory and non-refractory pain. Evidence for the refractory group was extrapolated to the whole group using an adjustment factor rather than fit the mapping to the refractory patients only. The review group have concerns over this methodology.
7. The base case incremental cost-effectiveness ratio (ICER) for pregabalin plus usual care as compared with usual care alone in patients with treatment-refractory neuropathic pain was estimated at €2,360 per quality adjusted life year (QALY). A probabilistic sensitivity analysis was also presented which indicated a 100% probability that pregabalin plus usual care was the most cost effective therapy at a willingness to pay threshold of €45,000/QALY. The allowance made for uncertainty was compromised by the inputs into the model as outlined in earlier sections of this report.
8. PCRS data indicates that in 2012 the HSE reimbursed pregabalin (for all indications) on the GMS and DPS at a cost of €47,293,171. In 2012 the expenditure for gabapentin was €5,726,723. In 2013, up to July, the HSE reimbursed pregabalin at a cost of €20,256,483 which projects annual total expenditure at over €40 million. Pfizer have submitted a budget impact analysis presenting three scenarios; Scenario 1 where generic pregabalin enters the market in July 2014; scenario 2 with generic pregabalin entering the market in January 2015 and scenario 3 where generic pregabalin enters the market in July 2015. The suggested budget impact for pregabalin in 2014 under scenarios 1, 2 and 3 were estimated at €18.2 million for scenario 1 and €30.1 million for scenarios 2 and 3. Pfizer suggest that the BI will decrease from 30.1million to €6.325million, in the year following introduction of a generic medicine. The review group do not consider this credible based on rate of generic prescribing.

9. The NCPE do not consider pregabalin to be cost effective for neuropathic pain in the Irish healthcare setting and therefore do not recommend reimbursement under the community drugs scheme in Ireland.