

Northern (NHS) Treatment Advisory Group

Treatment Appraisal: Decision Summary

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| Date | 5 th September 2017 |
| Appraisal & Details | <p>Paliperidone long acting injection (Xeplion®) and Paliperidone 3 monthly injection (Trevicta®) Janssen-Cilag for schizophrenia.</p> <p>The Northern (NHS) Treatment Advisory Group considered a re-appraisal of the recommendation on the use of paliperidone long acting injection (LAI) within its licensed indication for the treatment of schizophrenia, as an alternative to risperidone long acting injection.</p> <p>Paliperidone 3 monthly injection may be considered for patients clinically stable for at least 4 months on 1 monthly paliperidone palmitate injection.</p> |
| Recommendation | <p>The Northern (NHS) Treatment Advisory Group recommends the use of Paliperidone LAI and 3-monthly injection as per its licensed indications and as outlined in <i>the updated Guidance on the Use of Antipsychotic Long-acting Injections in the North of England.</i></p> |
| Clinical evidence summary | <p>Paliperidone LAI was shown to be non-inferior to risperidone LAI in two short-term studies which incorporated the licensed initiation dosing schedule. In another 33 week study, paliperidone LAI significantly delayed time to relapse compared with placebo and efficacy was maintained for up to 52-weeks as assessed by improvements in mean PANSS scores.</p> <p>Paliperidone 3 monthly injection was evaluated in two phase III trials; one looking at relapse prevention and efficacy and safety against placebo and one comparing use against the monthly preparation. Paliperidone levels were measured and found to be consistent during maintenance phase and similar to corresponding monthly doses. The tolerability and effectiveness was also found to be similar to previous trials with monthly paliperidone.</p> |
| Safety | <p>The overall safety profile of paliperidone appears comparable to the established safety profile of its related compounds, paliperidone and risperidone. There were no new safety signals from either short or long term phase III studies. In the pivotal comparative study with risperidone LAI, insomnia, injection site pain, and anxiety occurred at a $\geq 2\%$ higher incidence in the paliperidone group than in the risperidone LAI group.</p> |
| Patient Perspective | <p>Paliperidone LAI is administered monthly compared to every two weeks for risperidone LAI, which would reduce visits to secondary care, and potentially fewer visits from community psychiatric nurses if required.</p> <p>An extended dose interval (+/- seven days from usual date of administration) offers the potential to support patient adherence and could therefore assure compliance when treating patients in the community setting. Flexibility allows care closer to home and in the community. Paliperidone LAI requires a smaller needle size compared to risperidone LAI, and can be administered into either the deltoid or gluteal muscle.</p> <p>Paliperidone 3 monthly injection offers a longer dosing interval, requiring only 4 administrations per year and greater flexibility in timing.</p> |
| Cost analysis summary | <p>The group noted that whilst overall net drug expenditure would increase in-line with the small increase in drug acquisition costs (£45 per patient per annum), overall savings in healthcare costs may result from the practical advantages of paliperidone LAI compared to risperidone LAI, such as a less frequent dosing</p> |

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| | <p>schedule, no requirement for reconstitution, and no need for refrigeration and therefore a reduction in wastage and finally no requirement for oral antipsychotic supplementation. The greatest scope for cost savings originates from the potentially reduced hospital in-patient care provided for dose initiation. Some of these savings may however be difficult to realise in practice and may not translate in direct financial savings to the NHS commissioning organisation.</p> <p>Paliperidone 3-monthly injection is the same price as monthly injections, therefore due to the lower numbers of injections required there will be some cost savings originating from lower numbers of clinic visits (4 vs 12) associated with its use, however as above these savings may be difficult to realise in practice.</p> |
| <p>Financial impact PbR: NA</p> | <p>If used as outlined in the guidance the financial impact of this recommendation is expected to be low.</p> |

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