Northern Treatment Advisory Group

Northern (NHS) Treatment Advisory Group

Treatment Appraisal: Decision Summary

Date	25th November 2014 (updated 25th February 2020)
Appraisal & Details	**Sativex® oramucosal spray for the management of non-MS pain.** The Northern (NHS) Treatment Advisory Group considered an appraisal of Sativex® (GW Pharma) for use outside its licensed indication for the treatment of non-MS chronic pain.
Recommendation	**The Northern (NHS) Treatment Advisory Group does not recommend the use of Sativex® for the management of non-MS pain.** Clinical evidence for the efficacy of Sativex® was considered to be of low quality and did not demonstrate a clear benefit. Combined with a high acquisition cost, Sativex® was considered unlikely to meet conventional cost-effectiveness criteria. In addition the group felt that the high placebo responses seen in clinical trials highlighted that non-pharmacological methods of pain management should be more widely available for the treatment of chronic pain. This recommendation is line with NICE NG144: Cannabis-based medicinal products, November 2019 which does not recommended the use of Cannabis-based medicinal products for the management of chronic pain unless as part of a clinical trial.
Clinical evidence summary	A number of randomised and non-randomised controlled studies of varying quality have examined the efficacy of Sativex® in the management of chronic non-MS related pain conditions. The main evidence base is for the use of Sativex® in the treatment of chronic refractory cancer-related pain, and neuropathic pain of various origins. The results of studies in patients with cancer are inconsistent, but suggest that Sativex may have a role as an adjunct to opioid therapy for the treatment of cancer-related pain. An on-going phase III trial may form the basis of regulatory application for a license in this indication. In patients with neuropathic pain of various origins the evidence for efficacy is limited, with only one study demonstrating that Sativex® has a positive analgesic effect when used in addition to existing analgesic therapy.
Safety	Adverse effects with Sativex® are frequent but are generally mild to moderate in severity, well tolerated and only led to withdrawal from studies in a few occasions. The most commonly reported adverse effects are dizziness, fatigue, somnolence, nausea, and dry mouth. Local oral lesions associated with application of Sativex® have been reported.
Patient Perspective	Selecting an effective treatment for chronic pain can be problematic since the extent to which pain responds to analgesics varies depending on both patient and pain characteristics. Many patients still experience inadequate pain relief despite being treated with strong opiates, and dose-limiting side effects and fear of dependence often limit their use at higher and potentially more effective doses. There are currently no licensed non-opioid treatments for patients with chronic pain who have an inadequate response to opioids, or experience significant adverse effects with these medications.
Cost analysis summary	The mean annual cost of Sativex® per patient for the treatment of cancer pain is estimated at £4,750. For the treatment of neuropathic pain the estimated annual cost is £5,625 per patient.

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Financial impact PbR: In-tariff	Sativex® is intended to be used as an adjunct to existing opioid therapy and is not expected to replace current treatments. The financial impact of this recommendation is expected to be nil.