BNSSG Health Community's Traffic Light System
Shared Care Guidance

Please complete all sections.
Type in the grey shaded areas (deleting the prompts for information in each section).

Section 1: Heading

Trust: United Brstol Healthcare Trust

Specialty / Department: Division of Medicine

Drug:Lacosamide

For the treatment / management of: Multi-drug resistant diabetic neuropathic pain

Section 2: Background

The prevalence of diabetes mellitus in England is expected to be in excess of 7% by 2010, as the impact of the obesity pandemic translates into an increase in Type 2 diabetes, coupled with the longer survival of the ageing population. Diabetic peripheral neuropathy affects 45-55% of patients with DM and of these about 10-15% will have moderate to severe diabetic neuropathic pain (DNP). Therefore, at any one time about 1250 people in the Bristol PCT catchment area will have significant DNP. The vast majority of these patients will be on multiple medications with significant side effects and yet will still be sub-optimally treated, emphasising the huge unmet clinical need for better and more effective treatment regimes for neuropathic pain.

Section 3: Treatment aims

Professor Wynick runs a monthly specialist out-patient clinic, focused on improving the medical treatment of patients with moderate to severe DNP. The clinic is based within the existing diabetic clinic. The main benefits of this DNP clinic are:-

- A major reduction in the number of patients multiply attending their GP surgeries for symptoms relating to DNP.
- Reduction in chronic pain scores associated with improved Quality of Life measures, leading to improved patient satisfaction.
- Access to one-stop-shopping at the diabetic clinic.

The currently approved pan-avon protocol for the management of DNP uses in sequence or in combination Amitriptyline, Gabapentinoids and Duloxitine. Patients that cannot tolerate these drugs due to side effects or in whom they have poor efficacy are left in the unenviable situation of having to live with severe and debilitating pain for many years. In 2007-8 Dr Dayan (Consultant Diabetologist) entered a number of his patients with DNP into the now published double-blind randomised Lacosamide study and the follow on open-label study (see references in section 15). Two patients were on Lacosamide for more than a year and responded very well in terms of a significant reduction in pain scores. It is these two patients that are now being prescribed Lacosamide at the same doses they received in the study ie 200mg BD. It is expected that up to an additional 5 patients/year will be identified who have moderate to severe DNP and are resistant to conventional treatments. Lacosamide is a new treatment licenced for epilepsy that is not yet licenced for the treatment of DNP. The mechanism of action of Lacosamide for DNP is not yet fully elucidated but is likely to be attributable to its known calcium and sodium channel modulatory activity.

Patients who are resistant to the above standard drugs used in the pan-avon protocol will be assessed by Professor Wynick in his specialist DNP clinic and considered for Lacosamide therapy. Prof Wynick will slowly titrate the dose of Lacosamide over 4-6 weeks up to a maximum of 200mg BD. Once patients are stable on a dose of Lacosamide with tolerable side effects (see section 6 below) and demonstrate clinical benefit in terms of a reduction in pain scores then joint care with the GP will be instituted.

Section 4: Treatment schedule

Lacosamide (Vimpat, UCB) 200mg BD. Long term therapy is envisages since DNP is a chronic condition that often persists for many years. Annual review in the specialist DNP clinic will be undertaken as long as the patient is on Lacosamide.

Section 5: Monitoring

None required

Section 6: Side-effects

Prolongations in PR interval with lacosamide have been observed in some clinical studies. Lacosamide will be used with caution in patients with known conduction problems or severe cardiac disease such as a history of myocardial infarction or heart failure. Caution will be exerted when treating elderly patients as they may be at an increased risk of cardiac disorders or when lacosamide is used in combination with medication known to be associated with PR prolongation.

At the dose of 200mg BD the most frequently reported adverse reactions were dizziness (7-8%), headache (7-8%), nausea (4-8%) and fatigue (6-7%), see papers attached. They were usually mild to moderate in intensity and the incidence and severity of CNS and gastrointestinal adverse reactions usually decreased over time.

Section 7: Drug interactions

None known

Section 8: Cautions and special recommendations

Reduce dose in patients with renal failure with a GFR of <30mls/min

Section 9: Advice to the patient

None

Section 10: Responsibilities for Secondary Care

1. Institute and titrate Lacosamide until the patient is stable (for at least 3 months). Prof Wynick will review the patients every 12-months whilst they are on Lacosamide.

Section 11: Responsibilities for Primary Care

1. No monitoring is needed. Since Professor Wynick will be reviewing the patients every 12 months no more needs to be done. In the event that additional problems develop in the interim then the GP should contact Prof Wynick.

Section 12: Contact details

Name	Organisation	Telephone number	Fax number	E-mail address	Availability
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Section 13: Document details

Date prepared:	13/8/09
Prepared by:	David Wynick
Date for review:	In 2 years
Document identification:	STP-Lacosamide

Section 14: Collaboration

Loacosamide will be used for the treatment of multi-drug resistant diabetic neuropathic pain by Dr Peter Brook in his pain clinic at UHB and may also be used by some of the consultant diabetologists at UHB (Drs Dayan and Bradley) and NBT (Profs Gale and Bingley).

Section 15: References

Efficacy and Safety of Lacosamide in Diabetic Neuropathic Pain. James P. Wymer, Jeffrey Simpson, David Sen, Sabine Bongardt on behalf of the Lacosamide SP742 Study Group. Clin J Pain 2009;25:376–385

Long-term oral lacosamide in painful diabetic neuropathy: A two-year open-label extension trial. Aziz Shaibani, Victor Biton, Richard Rauck, Brigitte Koch, Jeffrey Simpson. European Journal of Pain 13 (2009) 458–463