NHS BOURNEMOUTH AND POOLE AND NHS DORSET

COMMISSIONING STATEMENT ON THE USE OF AMIFAMPRIDINE (FIRDAPSE®) IN LAMBERT-EATON MYASTHENIC SYNDROME

Amifampridine (Firdapse®) will not be routinely commissioned for the treatment of Lambert-Eaton Myasthenic Syndrome.

1. BACKGROUND INFORMATION

1.1. Amifampridine is 3,4-diaminopyridine (phosphate form). It is recently been given market authorization under the European Orphan Drugs legislation.

1.2. Amifampridine is indicated for symptomatic treatment of Lambert-Easton Myasthenic Syndrome (LEMS)[2].

1.3. LEMS is a chronic progressive debilitating condition of presynaptic neuromuscular transmission. It is caused by insufficient release of a chemical neurotransmitter called acetylcholine from the synaptic vesicles resulting in impaired nerve signal transmission. In 75 to 95% of cases the aetiology can be traced to auto antibodies that are directed against gated calcium channels.

1.4. The symptoms of LEMS vary in severity but are characterised by muscle weakness and excessive fatigue (especially of the legs and trunk), drooping eyelids, and speech impairment. Sensory disturbances such as numbness or tingling are also common. Other features include dry eyes dry mouth, constipation and impaired sweating amongst other symptoms. The onset of symptoms is gradual and insidious.

1.5. LEMS is strongly associated with cancer, especially small cell lung cancer (SCLC). It is estimated that about 3% of patients with SCLC have LEMS and 40 to 60% of patients with LEMS have SCLC and 5% have other cancers. Where LEMS occurs in the absence of a cancer it is often associated with an autoimmune disorder.

1.6. LEMS is a rare condition with the prevalence estimated at 5 cases per 2 million. It is therefore estimated that there are 150 patients with LEMS in the UK. Annual incidence is estimated at 1 per 2.5 million of the population.

2. EVIDENCE SUMMARY

2.1. The Scottish Medicines Consortium (SMC) published their advice on amifampridine phosphate (Firdapse®) during 2012. It is not recommended for use in NHS Scotland.

2.2. The SMC advice states:

2.3. *There are no clinical data for amifampridine phosphate and efficacy has been extrapolated from studies of amifampridine base (3,4-diaminopyridine), to which amifampridine phosphate has been accepted to be bioequivalent by the European Medicines Agency. In randomized controlled studies with patients with LEMS, 3,4-diaminopyridine treatment was associated with greater improvement in muscle strength and neuromuscular transmission than placebo.*

The submitting company's justification of the treatment's cost in relation to its benefits was not sufficient and in addition, the company did not present a sufficiently robust economic analysis to gain acceptance by the SMC.

2.4. Further details of the economic analyses are available in the SMC report[1]. This includes estimates of the cost per quality adjusted life year (QALY) for this treatment, which, at £92,267 fall outside the range considered to be acceptable for use of a treatment in England.

3. COMMISSIONING POSITION

3.1. Amifampridine (Firdapse®) will not be routinely commissioned by the cluster PCTs for the treatment of Lambert-Eaton Myasthenic Syndrome.

References

1. Scottish Medicines Consortium – Amifampridine 10mg tablet, as phosphate (Firdapse®). SMC no (660/10). July 2012. Available from:

www.scottishmedicines.org.uk/files/advice/amifampridine_phosphate_Firdapse_FINAL_July_2012_for_website.pdf

2. BNF (September 2012) www.bnf.org

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