Northern Treatment Advisory Group

Northern (NHS) Treatment Advisory Group

Treatment Appraisal: Decision Summary

Date	3rd June 2014
Appraisal & Details	**Dapoxetine (Priligy®▼) for Premature Ejaculation.** The Northern (NHS) Treatment Advisory Group considered an appraisal of Dapoxetine (Priligy®▼,Menarini Farmaceutica Internazionale SRL) for use in accordance within its licensed indication for "on demand" treatment of premature ejaculation in adult men aged 18 to 64 years.
Recommendation	**The Northern (NHS) Treatment Advisory Group does not recommend the use of dapoxetine for premature ejaculation.** The group was concerned with the lack of any cost effectiveness and long term safety data. There were also concerns around the lack of consistency in diagnosis and the lack of any published active comparator trials.
Clinical evidence summary	The group considered the evidence from pooled data from five phase III placebo controlled trials and noted that the primary end point of intravaginal ejaculation latency time (IELT) was increased from a baseline of 0.9 minutes to 3.1 minutes (30mg) and 3.6 minutes (60mg) and 1.9 minutes (placebo) which gives an overall increase of 1.2 and 1.6 minutes (vs. placebo). A minimum clinically important difference for IELT has not been established.
Safety	Adverse events reported in clinical trials (24 weeks) were consistent with the established adverse effect profile of SSRIs with the exception of syncope which is a dose dependant side effect of dapoxetine. Dapoxetine is contraindicated in those patients with significant pathological cardiac conditions. (i.e. heart failure, ischaemic heart disease etc).
Patient Perspective	There are no reliable estimates for the prevalence of persistent PE within the UK. The impact of persistent PE on psychological wellbeing and personal relationships is likely to vary considerably. European guidelines report that PE can have a negative impact beyond sexual relationships however not all men with short IELT experience personal distress or interpersonal difficulty and few seek medical help. For those that do seek help non pharmacological therapies and off label SSRIs are currently offered.
Cost analysis summary	There are no cost effectiveness data available for the use of dapoxetine, however the cost of dapoxetine used 3-6 times a month is significantly higher than the cost of off label SSRIs; with dapoxetine treatment costing more than ten times the cost of paroxetine and fluoxetine. It has been suggested that fewer than 2% of men (18-64) may have severe PE and of these 25% will seek treatment and 70% of these will be suitable for dapoxetine. Based on these figures it can be estimated that 200 men per 100,000 populations may be eligible for treatment with dapoxetine. It is estimated therefore that treatment costs for dapoxetine could be approximately £50,000 per 100,000 populations.
Financial impact **PbR: In-tariff**	Potential costs would need to include the costs of referral into an appropriate specialist outpatient clinic as the license requirement to carry out a detailed evaluation of PE and establish an IELT of less than two minutes will be challenging in primary care. The financial impact of this recommendation is expected to be nil.