Hertfordshire and West Essex Integrated Care System

NHS Hertfordshire and West Essex Integrated Care Board

DAPOXETINE FOR THE TREATMENT OF PREMATURE EJACULATION
NOT RECOMMENDED

Name: generic (trade)	What it is	Indication	Date of decision	Decision status	NICE Guidance
Dapoxetine (Priligy®)	Short acting selective serotonin reuptake inhibitor (SSRI)	Treatment of premature ejaculation (PE) in adult men aged 18 to 64 years	HMMC January 2014	Final	NICE - None

Recommendation: NOT RECOMMENDED for prescribing in primary or secondary care.

Double red

Dapoxetine is a short acting SSRI licensed for the treatment of premature ejaculation in men aged 18-64 years who meet the following criteria:

- An intravaginal ejaculatory latency time (IELT) of less than two minutes; **and**
- Persistent or recurrent ejaculation with minimal sexual stimulation before, on, or shortly after penetration and before the patient wishes; **and**
- Marked personal distress or interpersonal difficulty as a consequence of PE; **and**
- Poor control over ejaculation; **and**
- A history of premature ejaculation in the majority of intercourse attempts over the prior 6 months.

- Dapoxetine dose is 30-60mg orally as required but maximum once every 24 hours.

EFFICACY

- Four short term published trials in nearly 5000 men showed increased time from penetration to ejaculation (IELT) in dapoxetine groups compared with placebo.
- Trials were not designed to compare the relative efficacy of the 2 doses of dapoxetine.
- There is no efficacy and safety data beyond 24 weeks and no active comparator arm was used in trials.
- Trials showed a large placebo effect.
- Inclusion criteria were restrictive and patients outside the trial population are likely to seek treatment.

SAFETY

- The most common adverse effects reported are nausea (11.0% and 22.2% in 30 mg and 60 mg prn dapoxetine groups, respectively), dizziness (5.8% and 10.9%), headache (5.6% and 8.8%), diarrhoea (3.5% and 6.9%), insomnia (2.1% and 3.9%) and fatigue (2.0% and 4.1%).
- Approximately 0.5% dapoxetine-exposed subjects in trials experienced syncope. Some subjects fell and sustained minor injuries. An orthostatic test should be performed and a careful history taken before initiating therapy.
- Daily use is not recommended as it was associated with withdrawal effects in clinical trials.

COST

- Dapoxetine is significantly more costly than alternative products used off-label for premature ejaculation.
- There is no information on cost effectiveness of dapoxetine.

PATIENT FACTORS

- IELT may not fully reflect patient perceived benefit of treatment.

Assessment against Ethical Framework

Evidence of Clinical Effectiveness

- Among men with moderate-to-severe PE, dapoxetine has been shown to increase the time from penetration to ejaculation to a greater extent than placebo. In four similar trials lasting 12 or 24 weeks, a total of 4,843 men with PE who broadly met the licensing criteria were randomised to on-demand use of dapoxetine 30 mg or 60 mg or matching placebo, one to three hours before anticipated sexual activity. The primary endpoint was the mean time from penetration to ejaculation, the intravaginal ejaculatory latency time (IELT), measured by a partner-operated stopwatch. The pooled mean IELT at 12 weeks was greater than the baseline value in all three groups. Both doses of dapoxetine also produced greater improvements than placebo in subject and partner reported secondary outcomes, including ejaculation-related interpersonal difficulty, personal distress and satisfaction with sexual intercourse. According to sub-group analysis of two trials, response to treatment may be limited among men with mild erectile dysfunction.

Cost of treatment and Cost Effectiveness

- Dapoxetine is more expensive than other available SSRIs
- No NHS cost-effectiveness analysis is available.
- Unclear whether the benefits of dapoxetine are sufficiently clinically important to warrant the additional cost.

The needs of the population

The needs of the population appear to be low as there are other available treatments which may be used, albeit in an off-label manner. PE is primarily a symptomatic disorder with no known clinical sequelae or complications and therefore may not be regarded as a priority for NHS funding.

The needs of the community

The needs of the community are considered moderate. The use of dapoxetine instead of less costly off label SSRIs or local anaesthetics could create a cost pressure which may have an impact on the local health economies which already have to identify savings.

Equity

No impact anticipated.

Policy Drivers

None identified

Implementability

No issues identified

References

- London New Drugs Group/London Medicines Evaluation Review, Dapoxetine for premature ejaculation, November 2013, http://www.medicinesresources.nhs.uk/upload/Dapoxetine_finalNov2013.pdf
- eMC Summary of Product Characteristics, Accessed 07/08/2019. http://www.medicines.org.uk/emc/medicine/28284/SPC/Priligy+30+mg+and+60+mg+film-coated+tablets/#tableOfContents
- NICE premature ejaculation:Dapoxetine,Evidence Summary [ESNM40] Published date: May 2014 https://www.nice.org.uk/advice/esnm40/chapter/Key-points-from-the-evidence

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Version	1.1 Harmonisation of Hertfordshire Medicines Management Committee (HMMC) guidance and West Essex Medicines Optimisation Programme Board (WEMOPB) guidance updates include: • Rebadging with HWE ICB and removal of Herts CCG headers
Developed by	HWE Pharmacy and Medicines Optimisation Team
Approved by	HMMC
Date approved/updated	HMMC January 2014 WEMOPB non-formulary
Review date:	The recommendation is based upon the evidence available at the time of publication. This recommendation will be reviewed upon request in the light of new evidence becoming available.
Superseded version	1.0