General Commissioning Policy

Treatment	Dapoxetine (Priligy®)
For the treatment of	Treatment of premature ejaculation
Background	Dapoxetine is a short acting selective serotonin-reuptake inhibitor licensed for the treatment of premature ejaculation (PE) in men aged 18 to 64 years of age who meet all of the following criteria: ☐ An intravaginal ejaculatory latency time (IELT) of less than two minutes ☐ Persistent or recurrent ejaculation with minimal sexual stimulation before, on, or shortly after penetration and before the patient wishes ☐ Marked personal distress or interpersonal difficulty as a consequence of PE ☐ Poor control over ejaculation ☐ A history of PE in the majority of intercourse attempts over the prior 6 months.
Commissioning position	Dapoxetine is not routinely commissioned.
Effective from	September 2016
Summary of evidence / rationale	The European Association of Urology guidelines (http://uroweb.org/guideline/male-sexual-dysfunction/?type=pocket-guidelines) recommend several psychological/ behavioural strategies before considering pharmacological options. Other pharmacological options to use are lidocaine-prilocaine cream, SSRIs (taken daily, unlicenced indication) and phosphodiesterase type 5 inhibitors. NICE ESNM40 (published May2014) summarised the clinical trial evidence and compared the greater cost of dapoxetine with other SSRIs (unlicenced indication). They also stated that pharmacological treatment of premature ejaculation may not be a priority for the NHS. **Clinical Studies**: Efficacy of Dapoxetine in the treatment of premature ejaculation McMahon G Clinical Medicine Insights; Journal of Reproductive Health 2011: 5 p25-39 This review looked at five randomized, placebo-controlled, phase 3 clinical trials. Treatment period ranged from 9-24 weeks, 6081 men, mean age 40.6 years (range 18-82 years) were enrolled with 4234 (69.6%) completing the studies. The DSM-IV-TR criteria and a baseline IELT < 2minutes on 75% of/=4 sexual intercourse events were used to enroll the subjects. Baseline average IELT was 0.9 minutes for patients overall. Outcome measures included stopwatch IELT, the premature ejaculation profile, a validated self administered 4 item tool that includes measures of perceived control over ejaculation, satisfaction with sexual intercourse, ejaculation-related personal distress. By week12, mean average IELT had increased to 3.1 and 3.6 minutes with dapoxetine 30 and 60mg respectively

Notes

1. This Policy will be reviewed in the light of new evidence, or guidance from NICE.
2. General Commissioning Policies are agreed by the Planning and Commissioning Committee on behalf of NHS Hull CCG.

(vs 1.9 minutes with placebo; p<0.001 for both).
Control over ejaculation was reported as "good" or "very good" by <1% of subjects at baseline and improved to 26.2% and 30.2% with dapoxetine 30 and 60mg respectively vs 11.2% with placebo by week 12, other results are shown in table below.

	Depoxetine		Placebo
	30mg (n=1613)	60mg (n=1611)	(n=1608)
Mean baseline IELT	0.9 minutes	0.9 minutes	0.9 minutes
Mean treatment IELT	3.1 minutes	3.6 minutes	1.9 minutes
"Good/very good" control			
-%baseline	0.3%	0.6%	0.5%
-% study end	26.2%	30.2%	11.2%
"Good/very good satisfaction			
% baseline	15.5%	14.7%	15.5%
% study end	37.9%	42.8%	24.4%
Quite a bit/extreme personal distress			
% baseline	73.5%	71.3%	69.7%
% study end	28.2%	22.2%	41.9%

The most frequently reported adverse effects were nausea, diarrhoea, headache, dizziness, insomnia, somnolence, fatigue and nasopharyngitis. Syncope occurred in 0.05%, 0.06% and 0.23% of subjects with placebo, dapoxetine 30mg, and dapoxetine 60mg respectively.

Points for consideration

- ☐ Clinical trials have shown it to be more effective than placebo, prolonging the time from penetration to ejaculation by between one and two minutes more than placebo.
- ☐ Concerns relating to the risk of syncope have been identified with the 60mg dose.
- ☐ Significant interactions with other drugs may limit dose to 30mg

It is widely available on websites via private prescriptions from internet pharmacies. This may lead to requests from patients for their GP to prescribe it on FP10.

Date	May 2017
Policy to be reviewed by	May 2019
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