NHS
Calderdale
Clinical Commissioning Group

Commissioning Statement

Treatment	**Dapoxetine** (Priligy®)
For the treatment of	Dapoxetine is indicated for the treatment of premature ejaculation in adult men aged 18 to 64 years
Commissioning position	**NHS Calderdale CCG does not routinely commission the use of dapoxetine for premature ejaculation**. The cost of dapoxetine is significantly greater than that of other selective serotonin-reuptake inhibitors (SSRIs) used off-label, the evidence for its use is limited and long-term safety outcomes are not available.
Date effective from	25 January 2017
Policy to be reviewed by	24 January 2020 (to be reviewed earlier if NICE issues guidance at an earlier date)
Background information	SSRIs can delay ejaculation and are therefore widely used 'off-label' for premature ejaculation[1]. Off label SSRIs and tricyclic antidepressants (TCAs) that have been used as a daily treatment for premature ejaculation are paroxetine, sertraline, fluoxetine, citalopram and clomipramine, according to the British Society for Sexual Medicine[2]. Dapoxetine is a short acting SSRI which is licensed for premature ejaculation[3] and offers a licensed therapeutic option compared to the use of other oral SSRIs. It is taken on a when required basis unlike other SSRIs which have to be taken daily. It should not be used to delay ejaculation in men who have not been diagnosed with premature ejaculation[3]. There are currently no other treatments for premature ejaculation licensed in the UK. SSRIs other than dapoxetine, topical anaesthetics (e.g. lidocaine/prilocaine cream) and phosphodiesterase inhibitors have been used off-label[2]. On-demand tramadol is an option where premature ejaculation co-exists with a need for analgesia. Pooled evidence from trials suggests that tramadol increases intravaginal ejaculatory latency time by a mean of 1.4 minutes versus placebo[4].
Summary of evidence/ rationale	**Safety**: Adverse effects of dapoxetine are broadly consistent with other SSRIs (the most common adverse effects are nausea, dizziness, headache, diarrhoea and somnolence)[3]. However there are concerns about an increased risk of syncope, especially at the higher dose. Across five trials, 0.06% of patients on the 30mg dose and 0.23% on the 60mg dose experienced syncope (versus 0.05% on placebo)[4] Some subjects fell and sustained minor injuries. An orthostatic test would be required and a careful history taken before initiating therapy[3]. Patients should be warned not to drink alcohol in combination with dapoxetine due to increase in adverse events, such as syncope. The Summary of Product Characteristics also recommends that a careful

appraisal of individual benefit risk of dapoxetine should be performed by the physician after the first four weeks of treatment (or at least after 6 doses of treatment) to determine whether continuing treatment with dapoxetine is appropriate. The clinical need of continuing and the benefit risk balance of treatment with dapoxetine should be re-evaluated at least every six months due to limited evidence of safety beyond 24 weeks[3].

Clinical effectiveness:
It is important to note that there is very limited data on long-term efficacy beyond 24 weeks[3].

There is some evidence for the efficacy of dapoxetine in the treatment of premature ejaculation. In five randomised controlled trials dapoxetine treated patients showed significantly longer times to ejaculation than placebo treated patients.[5] Trials have demonstrated that dapoxetine prolongs the time from penetration to ejaculation by between one and two minutes more than placebo. This represents a 2.5- to 3-fold increase compared to baseline: however clinical experience suggests a 3- to 4-fold increase as being clinically significant[6].

Significant improvements in premature ejaculation with dapoxetine were also evidenced by the more subjective secondary endpoints of patient-reported outcomes. These included control of premature ejaculation, satisfaction with sexual intercourse, personal distress relating to ejaculation and interpersonal difficulties relating to ejaculation, as well as how the patient perceived improvements in premature ejaculation[7].

Cost effectiveness/resource impact:
The Drug and Therapeutics Bulletin concluded that cost-effectiveness data for dapoxetine are lacking[6].

The cost of dapoxetine is significantly greater than that of other SSRIs used off-label, with dapoxetine treatment costing approximately 30 or 40 times the cost of sertraline or fluoxetine. The potential economic impact of dapoxetine is uncertain as premature ejaculation is a poorly understood disorder with no single, widely-recognised, evidence-based definition[6].

The Scottish Medicines Consortium and the All Wales Medicines Strategy Group do not recommend the use of dapoxetine, due to submissions not being made to either committee[8,9].

Equity of access
It is recommended that a thorough evaluation of premature ejaculation and sexual dysfunction, including detailed history and impact on psychological health and/or relationships, as well as consideration of risk factors for syncope, will be needed before prescribing dapoxetine.

Such assessment and the licence requirement to establish an intravaginal ejaculatory latency time of less than two minutes may be challenging and would need specialist assessment before initiation[3].

	1. Hatzimouratidis K (Chair), Eardley I, Giuliano F et al. Guidelines on male sexual dysfunction: erectile dysfunction and premature ejaculation. Updated March 2015. Accessed from http://uroweb.org/wp-content/uploads/14-Male-Sexual-Dysfunction_LR1.pdf on 14.7.16 2. British Society for Sexual Medicine. Treatment algorithm for premature ejaculation. July 2013. Accessed from http://www.bssm.org.uk/downloads/BSSM-algorithm-premature-ejaculation-v4.pdf on 14.7.16 3. DataPharm. Priligy 30mg and 60mg film-coated tablets. A. Menarini Farmaceutica Internazionale SRL. Summary of product characteristics. Last updated on electronic medicines compendium on 15.4.14. Accessed from https://www.medicines.org.uk/emc/medicine/28284 on 14.7.16 4. Cooper K, James MM-S, Kaltenthaler E et al. Interventions to treat premature ejaculation. Health Technology Assessment 2015;19:1366-2046 5. Midlands Therapeutics Review and Advisory Committee Commissioning Support. Dapoxetine (Priligy®) For the treatment of premature ejaculation. Accessed from http://centreformedicinesoptimisation.co.uk/download/dec9e4d53e9f1761954ecf08437c0ccf/Dapoxetine-Verdict-Nov-2013.pdf on 14.7.16 6. Anon. Dapoxetine for premature ejaculation. Drug & Therapeutics Bulletin: vol52,3,March2014 7. London New Drugs Group/London Medicines Evaluation Network Review: Dapoxetine (Priligy®) for premature ejaculation: November 2013. Accessed from http://www.medicinesresources.nhs.uk/upload/Dapoxetine_finalNov2013.pdf on 14.7.16 8. Scottish Medicines Consortium. dapoxetine (Priligy). Advice 7.7.2014 accessed from http://www.scottishmedicines.org.uk/SMC_Advice/Advice/987_14_dapoxetine_Priligy_Non_Submission/dapoxetine_Priligy_Non_Submission on 14.7.16 9. All Wales Medicines Strategy Group. dapoxetine (Priligy®). Advice 7.8.2012 accessed from http://www.awmsg.org/awmsgonline/app/appraisalinfo/1671 on 14.7.2016
Contact for this policy	**Medicines Management Lead**