Recommendation on the use of dapoxetine for the treatment of premature ejaculation

Recommendation

Dapoxetine is not routinely funded on the local NHS for the treatment of premature ejaculation.

Practices are asked NOT to prescribe Dapoxetine for this indication.

The Kent and Medway Policy Recommendation and Guidance Committee (PRGC) considered the evidence, baseline position, other CCG policies and the views and opinions of local experts. All decisions were made with reference to the Ethical Framework. Taking these into account the PRGC recommend that:

- Dapoxetine is not routinely funded on the local NHS for the treatment of premature ejaculation.

Policy:	**PR 2014-07: Dapoxetine for premature ejaculation (PE)**
Issue date:	**June 2014**
Review date:	**June 2017**

Recommendation:

The Kent and Medway Policy Recommendation and Guidance Committee (PRGC) considered the evidence, baseline position, other CCG policies and the views and opinions of local experts. All decisions were made with reference to the Ethical Framework. Taking these into account the PRGC recommended that:

☐ Dapoxetine is not routinely funded on the local NHS for the treatment of premature ejaculation

This policy recommendation will be reviewed in light of new evidence or national guidance.

Commissioners in Kent and Medway will always consider appropriate individual funding requests (IFRs) through their IFR process.

Supporting documents

- Health Care Intervention Appraisal and Guidance (HCiAG) team (2014) *Dapoxetine (Priligy®) for the treatment of premature ejaculation (PE) – Scoping report*

Approved by: East Kent Prescribing Group *(Representing Ashford CCG, Canterbury and Coastal CCG, South Kent Coast CCG and Thanet CCG)*
Date: April 2015
Address: c/o *Thanet Clinical Commissioning Group, Thanet District Council Offices, Margate CT9 1XZ*
Contact: T: 03000 424612 | E: accg.eastkentprescribing@nhs.net

Key findings and rationale.

What is premature ejaculation (PE)?
Although PE is a common male sexual dysfunction, it is poorly understood. Multiple definitions of PE have been proposed. All take into account the time to ejaculation (usually described by intravaginal ejaculatory latency time [IELT]), the inability to control or delay ejaculation, and negative consequences (bother/distress) from PE. PE can be categorised as lifelong (primary) or acquired (secondary). Observational studies suggest PE is associated with adverse psychosocial and quality of life consequences, including negative effects on partner relationships.

What is the prevalence of PE?
Reliable information on the prevalence of lifelong and acquired PE in the general male population is lacking. The prevalence of PE has been reported as 20–30% using older definitions that do not contain an IELT cut-off. Limited data suggests that the prevalence of lifelong PE, defined as an IELT of <1–2 minutes, is about 2–5%. The lower prevalence estimates are more consistent with the numbers of men who present for treatment of PE.

How is PE currently treated?
Non-drug options include psychological and behavioral strategies. Drug therapy includes on-demand topical anaesthetic agents and daily off-label selective serotonin reuptake inhibitors (SSRIs). According to 2014 European Association of Urology (EAU) guidelines, treatment is limited to psychosexual counselling and education in men for whom PE causes few problems, while pharmacotherapy is the basis of treatment for lifelong PE.

What is dapoxetine?
Dapoxetine (Priligy®, A. Menarini Farmaceutica Internazionale SRL) is the first oral pharmacological treatment for PE to be licensed in the UK. Unlike other SSRIs, which are used off-label and taken daily, dapoxetine is short-acting and taken as required (maximum once a day). It is only indicated in men with PE who meet certain criteria (see SPC for more information). The recommended dose is 30mg; the maximum dose of 60mg may be used by patients with insufficient response and no moderate or severe adverse effects or prodromal symptoms suggestive of syncope.

What is the evidence base for dapoxetine?
Dapoxetine has been evaluated in five randomised, double-blind, placebo-controlled phase 3 trials conducted over 9–24 weeks in 6,081 people with PE. When data were pooled, dapoxetine increased IELT by ~1 minute vs placebo (a 2.5 and 3-fold increase over baseline for dapoxetine 30mg and 60mg respectively vs 1.6 for placebo). Although these improvements were statistically significant, their clinical significance could be considered marginal. In addition, subjective outcomes improved significantly with both doses of dapoxetine vs placebo. The percentage of participants reporting that their PE was 'better' or 'much better' at week 12 was 31%, 38% and 14% for dapoxetine 30mg,

60mg and placebo respectively. Most AEs were mild to moderate in severity and similar to those of other SSRIs, most commonly nausea, dizziness, headache and diarrhoea. The incidence and severity of adverse events is higher with the 60mg dose.

No studies directly compared on-demand dapoxetine with other drugs for PE; indirect comparisons suggest daily off-label SSRIs may be (at least) as effective as on-demand dapoxetine. Also, published data on the long-term safety and efficacy of on-demand dapoxetine are lacking, while the applicability of study results to the wider population may be limited as only heterosexual men in monogamous relationships were included in the studies, and most were aged ≤49 years.

What is the comparative cost of dapoxetine?
The cost of dapoxetine used 3–6 times a month, is substantially more than that of other SSRIs – most of which are available generically – used off-label. According to a budget impact analysis performed by the company, drug costs (per 100,000 population) assuming 3 tablets per month were £4,647, £9,050 and £13,452 in years 1 (20% uptake), 2 (40% uptake) and 3 (60% uptake) respectively. Off-set costs such as reduced outpatient referrals are currently unclear. Treatment of PE does not appear to have been prioritised for additional investment by Kent and Medway CCGs and the cost-effectiveness of on-demand dapoxetine for PE has not been established.

Approved by: East Kent Prescribing Group *(Representing Ashford CCG, Canterbury and Coastal CCG, South Kent Coast CCG and Thanet CCG)*
Date: April 2015
Address: c/o *Thanet Clinical Commissioning Group, Thanet District Council Offices, Margate CT9 1XZ*
Contact: T: 03000 424612 | E: accg.eastkentprescribing@nhs.net