Avanafil (Spedra®) for the treatment of adults with erectile dysfunction

NHS Devon

Commissioning policy

The routine commissioning of avanafil is not accepted in Devon for the treatment of adult men with erectile dysfunction (ED).

The Formulary Interface Group should not include this in locally defined treatment recommendations.

Rationale for the decision

The efficacy of avanafil has been demonstrated in three double-blind randomised control trials comparing avanafil with placebo in men with mild to severe erectile dysfunction (ED). Avanafil was found to demonstrate a significantly greater improvement in measures of erectile function compared to placebo, at all three treatment doses. This difference was demonstrated in each of the three RCTs, which considered the use of avanafil in a different patient population; namely, the general population, diabetic patients and patients with a history of radical prostatectomy. The long term efficacy, safety and tolerability of avanafil is further supported by a 52-week open-label extension trial. There are no direct head-to-head comparisons between avanafil and other phosphodiesterase type 5 (PDE-5) inhibitors and indirect comparisons are limited by differences in study design.

Generic sildenafil represents the first-line PDE-5 inhibitor of choice, as it is an effective treatment which is significantly cheaper than the other PDE-5 inhibitors currently licensed for the treatment of ED. There is no specific evidence which demonstrates the effectiveness of avanafil in patients who have responded inadequately to sildenafil. Patients with a history of consistent treatment failure (defined as failure to respond to ≥ two PDE-5 inhibitors) or dose-limiting adverse events with other PDE-5 inhibitors, were excluded from the avanafil trials.

Furthermore, efficacy responses for men known to have failed one oral ED treatment were not reported separately.

There are currently no published cost-effectiveness analyses conducted for avanafil from the perspective of the NHS. Although avanafil is currently cheaper than the other second-line PDE-5 inhibitors available, namely tadalafil and vardenafil, both of these drugs are due to lose their patents in 2017 and 2018 respectively, with large reductions in acquisition cost subsequently anticipated. As a result any savings made following the initiation of avanafil may be short lived and therefore future prescribing represents relatively poor value. The ongoing cost of prescribing avanafil after the patent losses of existing PDE-5 inhibitors was considered too great to support the commissioning of avanafil, given that effective treatment options for ED are already available.

Guidance notes on exceptionality

This general policy does not replace clinical judgement on the appropriate treatment of an individual patient.

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