Ospemifene in vulvovaginal atrophy: Added benefit not proven

August 10 2016

Ospemifene (tradename: Senshio) is approved for the treatment of moderate to severe symptomatic vulvovaginal atrophy (VVA) in post-menopausal women who are not candidates for local vaginal oestrogen therapy. The drug has been on the market in Germany since May 2016. In an early benefit assessment, the German Institute for Quality and Efficiency in Health Care (IQWiG) has now examined whether it has advantages or disadvantages in comparison with the appropriate comparator therapy.

As none of the 3 studies presented by the manufacturer is suited to derive such conclusions, IQWiG concludes that an added benefit of ospemifene over the comparator therapy is not proven.

Oestrogen receptor modulator instead of oestrogen

Due to a decrease in oestrogen levels in menopause, the vaginal mucosa regresses and some women may experience vaginal dryness that can lead to pain or itching. Vaginal oestrogen therapy is not suitable for some affected women, for example, due to intolerable side effects.

Ospemifene is a drug from the class of selective oestrogen receptor modulators; these agents and their main metabolic products bind to oestrogen receptors instead of oestrogen and thus have a similar effect to the hormone.

Studies unsuitable

The Federal Joint Committee (G-BA) specified best supportive care or systemic hormone therapy as appropriate comparator therapies. The manufacturer cited 3 randomized controlled trials; however, they are all unsuitable for drawing conclusions on the added benefit of ospemifene. None of the studies specifically included women who were not candidates for local vaginal oestrogen therapy. With a duration of 12 weeks, 2 of the studies were much too short. In one of the studies, symptom severity was not an explicit inclusion criterion.

In addition, the women in the control arms of the studies were allowed neither to use other non-hormonal treatments (except for a specified lubricant) nor to continue systemic hormone therapy already started. Hence the requirements for the appropriate comparator therapy were not correctly implemented. As no suitable data on the research question are available, an added benefit of ospemifene over the appropriate comparator therapy is not proven.

G-BA decides on the extent of added benefit

The dossier assessment is part of the early benefit assessment according to the Act on the Reform of the Market for Medicinal Products (AMNOG) supervised by the Federal Joint Committee (G-BA). After publication of the dossier assessment, the G-BA conducts a commenting procedure and makes a final decision on the extent of the added benefit.

Provided by Institute for Quality and Efficiency in Health Care