NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Fezolinetant for treating moderate to severe vasomotor symptoms associated with the menopause ID5071

Draft scope

Remit/evaluation objective

To appraise the clinical and cost effectiveness of fezolinetant within its marketing authorisation for treating moderate to severe vasomotor symptoms associated with the menopause.

Background

The menopause occurs when menstruation stops and the end of natural reproductive life is reached. Usually, it is defined as having occurred when there has been no naturally occurring period for 12 consecutive months. It is a natural part of ageing. Changes associated with menopause occur when the ovaries stop maturing eggs and secreting oestrogen and progesterone. The experience of symptoms varies (length and severity) but most people will have some vasomotor symptoms associated with the decrease in oestrogen. Vasomotor symptoms include hot flushes and night sweats caused by constriction and dilatation of blood vessels in the skin that can lead to a sudden increase in blood flow to allow heat loss. Vasomotor symptoms have been linked to problems with sleep, quality of life and depression.

Menopause usually occurs between age 45 and 55 with an average age of 51 years. The prevalence of problematic vasomotor symptoms that need treatment is estimated to be 25%[1], and the prevalence decreases with age to 15% at age 55 to 59, 6% at age 60-69 and only 3% at over 70[2]. However, medical intervention is often not sought so the true prevalence of vasomotor symptoms may be much higher, with studies showing that up to 80% may experience vasomotor symptoms as part of the menopause[3].

Hormone replacement therapy (HRT) is the main treatment option for vasomotor symptoms in menopause. NICE recommends the following treatment options for vasomotor symptoms associated with menopause:

- oestrogen and progestogen for those with a uterus; or oestrogen alone for those without a uterus (NG23).
- selective serotonin reuptake inhibitor (SSRI) antidepressants for those with breast cancer, but not for those taking tamoxifen (NG101).

NG101 also notes that HRT should be stopped if breast cancer is diagnosed and should not be offered routinely when there is a history of breast cancer unless in exceptional circumstances.

When HRT is not suitable, treatments for VMS include SSRIs, serotonin and norepinephrine reuptake inhibitors (SNRIs), clonidine, and anti-convulsants such as gabapentin and pregabalin.

The technology

Fezolinetant (Veoza, Astellas Pharma) has a marketing authorisation in the UK for treating moderate to severe vasomotor symptoms associated with the menopause.

Intervention(s)	Fezolinetant
Population(s)	People with moderate to severe vasomotor symptoms associated with the menopause

Comparators	**People for whom HRT is suitable:**
	• Hormonal pharmaceutical treatments (such as oestrogen and progestogen combination, or oestrogen alone)
	People for whom HRT is not considered suitable:
	• No pharmacological treatment
	• Non-hormonal pharmacological treatments, for example:
	  ○ anti-depressants such as selective serotonin reuptake inhibitors (SSRIs) and serotonin and norepinephrine reuptake inhibitors (SNRIs)
	  ○ clonidine
	  ○ anti-convulsants such as gabapentin and pregabalin.

Outcomes	The outcome measures to be considered include: • frequency of vasomotor symptoms • severity of vasomotor symptoms • sleep disturbance • psychological symptoms (anxiety, low mood) • adverse effects of treatment • health-related quality of life.
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective.

Other considerations	Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations	**Related NICE guidelines:** Menopause: diagnosis and management (2019). NICE guideline 23. Current undergoing partial update. Early and locally advanced breast cancer: diagnosis and management (2018). NICE guideline 101. **Related interventional procedures:** Removal, preservation and subsequent reimplantation of ovarian tissue to prevent symptoms from the menopause (2022). NICE interventional procedures guidance 738. **Related quality standards:** Menopause (2017). NICE quality standard 143.
Related National Policy	The NHS Long Term Plan, 2019. NHS Long Term Plan Department for Health and Social Care, 2022. Women's Health Strategy, priority area 13

Questions for consultation

Where do you consider fezolinetant will fit into the existing care pathway for menopause?

What are the main treatments used in clinical practice for people for whom HRT is not considered suitable?

Please select from the following, will fezolinetant be:

A. Prescribed in primary care with routine follow-up in primary care
B. Prescribed in secondary care with routine follow-up in primary care
C. Prescribed in secondary care with routine follow-up in secondary care
D. Other (please give details):

For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.

Would fezolinetant be a candidate for managed access?

Do you consider that the use of fezolinetant can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected

characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which fezolinetant is licensed;
- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

NICE intends to evaluate this technology through its Single Technology Appraisal process. (Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

References

1. Hickey, M., Szabo, R.A. and Hunter, M.S. (2017) Non-hormonal treatments for menopausal symptoms. British Medical Journal 359. [Abstract]
2. BMJ Best Practice. Menopause. Accessed 23 May 2024.
3. Woods, N.F. and Mitchell, E.S. (2005) Symptoms during the menopause: prevalence, severity, trajectory, and significance in women's lives. American Journal of Medicine 118(S12B), 14-24. [Abstract]