**DERBYSHIRE LINCONSHIRE & NOTTINGHAMSHIRE (DLN) AREA PRESCRIBING COMMITTEE (APC)**

# FEZOLINETANT (VEOZA®) PRIMARY CARE PATHWAY, AFTER SPECIALIST ADVICE

**Management of Moderate to Severe Vasomotor Symptoms (VMS) Associated with Menopause**

In accordance with NICE TA1143, NICE NG23, MHRA Drug Safety Update and the fezolinetant (VEOZA®) Summary of Product Characteristics (SmPC).

## Executive Summary

Fezolinetant (VEOZA®) is a selective neurokinin-3 (NK3) receptor antagonist recommended by NICE TA1143 for the treatment of moderate-to-severe vasomotor symptoms (VMS) associated with menopause when first line treatments of hormone replacement therapy (HRT), and second line treatments of selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), and gabapentin where appropriate and clinically justified, is unsuitable, contraindicated, not tolerated, or declined.

## Formulary Position

| Derby and Derbyshire | Lincolnshire | Nottingham and Nottinghamshire |
|---|---|---|
| Green - after consultant/specialist recommendation. | Amber 2 - suitable to be prescribed in primary care after specialist recommendation or initiation. | Amber 2 - suitable to be prescribed in primary care / general practice after specialist recommendation or initiation. |

All initiations in primary care must be channeled via secondary care specialist Advice & Guidance (A&G) service. Following specialist review and written advice, routine patients may be initiated and monitored in primary care, while more complex patients should be referred directly to secondary care specialist services before treatment.

## Assessing suitability for fezolinetant

Patients should have:

- Moderate to severe vasomotor symptoms associated with menopause.
- First line option HRT is unsuitable (contraindicated, not tolerated or declined).
- Second line non-hormonal options such as SSRIs/SNRIs, gabapentin where appropriate and clinically justified, are unsuitable (contraindicated, not tolerated or declined).
- ALT and AST less than 2 x ULN and bilirubin less than 2 x ULN.
- eGFR ≥30 mL/min/1.73 $m^2$.
- Not pregnant or breastfeeding.
- No clinically significant drug interactions.
- No contraindications listed in the SmPC.

Where HRT remains appropriate, management should follow NICE NG23.

## Patient Counselling

Explain that symptom improvement may begin from approximately 4 weeks. Fezolinetant is taken once daily. Discuss mandatory liver function monitoring and advise urgent review if symptoms of liver injury develop.

Urgent symptoms include new onset fatigue, nausea, vomiting, loss of appetite, abdominal pain, pruritus, dark urine, pale stools, and yellowing of the skin or eyes.

## Specialist Advice & Guidance (All Initiations in primary care)

All patients should be discussed through secondary care specialist Advice & Guidance service before initiation in primary care.

Direct referral before initiation is recommended for:

Examples
- Age >65 years
- Known liver disease or increased liver risk
- Abnormal LFTs not meeting absolute non-initiation criteria
- Child-Pugh hepatic impairment
- eGFR <30 mL/min/1.73 $m^2$
- Current or previous breast cancer
- Other oestrogen-dependent malignancy
- History of seizures/convulsive disorders
- Diagnostic or management uncertainty

## Contraindications and Important Cautions

Do not prescribe if ALT/AST ≥2×ULN, bilirubin ≥2×ULN, active liver disease, eGFR <30 mL/min/1.73 $m^2$, pregnancy, hypersensitivity, or with strong/moderate CYP1A2 inhibitors such as fluvoxamine, mexiletine and ciprofloxacin, or with combined hormonal contraceptives.

Use individual benefit-risk assessment for previous breast cancer, previous oestrogen-dependent malignancy and seizure disorders.

**Concomitant use with oestrogen-containing HRT has not been studied and is therefore not recommended.**

## Liver Function Monitoring Schedule

Monitor ALT, AST and total bilirubin at baseline, monthly for the first 3 months, then thereafter only if clinically indicated. Repeat immediately if symptoms suggest liver dysfunction.

## Discontinuation Criteria

Stop fezolinetant if:
- ALT/AST ≥3×ULN with bilirubin >2×ULN
- ALT/AST ≥3×ULN with symptoms of liver injury
- ALT/AST >5×ULN

Continue monitoring until liver function normalises.

## Review of Treatment (8–12 Weeks After Initiation)

Assess reduction in hot flushes, night sweats, quality of life, adverse effects and completion of monitoring. Continue if effective; otherwise, specialist referral.

## GP Responsibilities

Following written specialist Advice & Guidance: confirm eligibility, arrange investigations, initiate routine patients, counsel patients, arrange monitoring, review at 8–12 weeks and continue prescribing where appropriate.

## Specialist Responsibilities

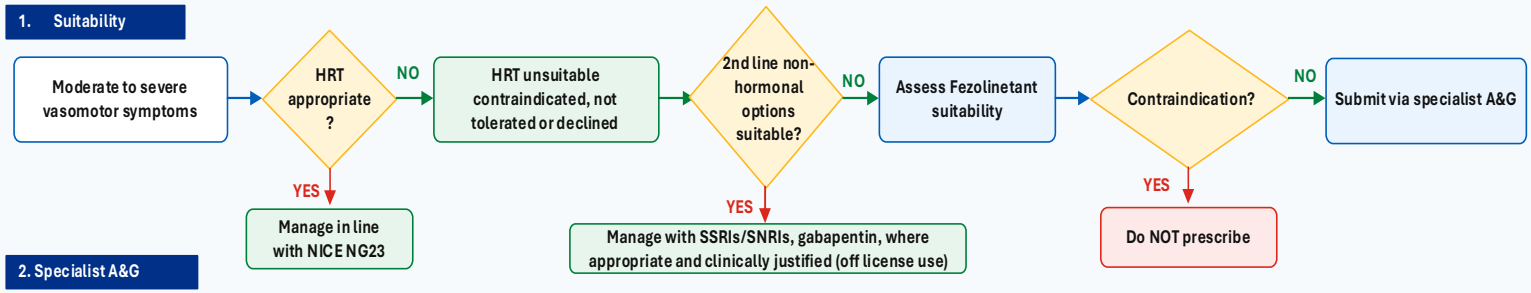
Provide Advice & Guidance for all initiation requests, assess suitability, perform benefit-risk assessment, advise on monitoring, recommend referral for complex cases and support ongoing management.

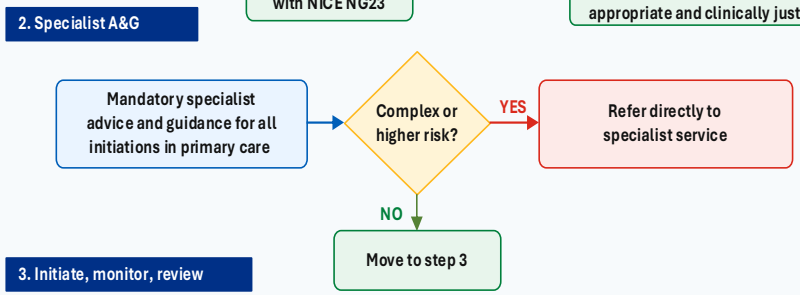
## Equality Impact Statement

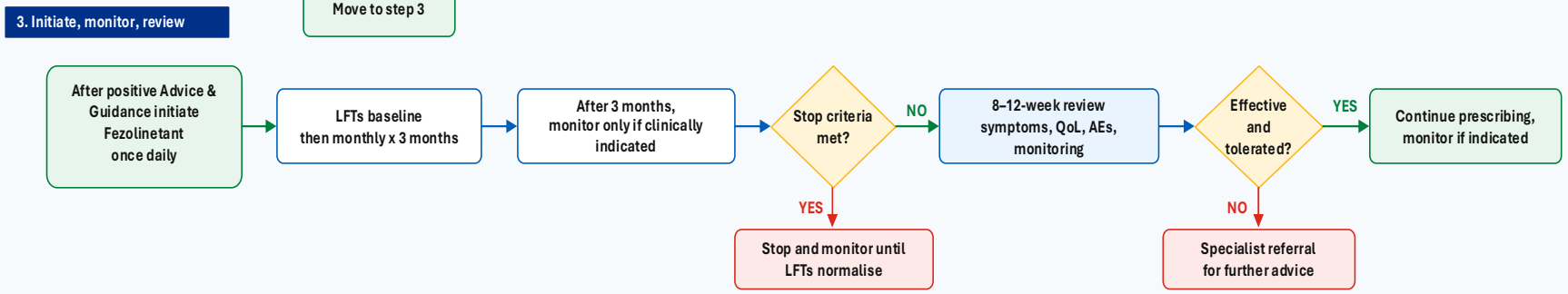
This pathway aims to promote equitable access to evidence-based, non-hormonal treatment options for menopause-related vasomotor symptoms and supports patients in making informed choices about their care.

# Fezolinetant initiation, monitoring and review pathway

All primary care initiations require secondary care specialist Advice & Guidance




**Eligibility and contraindication screen**

Moderate to severe menopause-associated VMS.
First line HRT options unsuitable.
Second-line non-hormonal options unsuitable.
ALT/AST /Bilirubin <2 x ULN.
eGFR ≥30 mL/min/1.73 $m^2$.
Not pregnant/breastfeeding.
No significant interactions or SmPC contraindications.
Do not prescribe if ALT/AST ≥2 x ULN, bilirubin ≥2 x ULN, active liver disease, hypersensitivity or with strong/moderate CYP1A2 inhibitor such as fluvoxamine, mexiletine and ciprofloxacin, or with combined hormonal contraceptives.

**Complex or higher-risk: refer before initiation**

Age >65 years.
Known liver disease/increased liver risk.
Abnormal LFTs not meeting absolute non-initiation criteria.
Child-Pugh impairment
Current/previous breast cancer or other oestrogen-dependent malignancy.
History of seizures/convulsive disorders.
Diagnostic/management uncertainty.

**Monitoring, counselling and stop criteria**

Counsel: once daily; improvement may begin from around 4 weeks; urgent review for liver injury symptoms.
Check ALT, AST, ALP, total bilirubin and direct bilirubin at baseline and monthly for first 3 months.
Stop if ALT/AST ≥3 x ULN with bilirubin >2 x ULN, ALT/AST ≥3 x ULN with symptoms, or ALT/AST >5 x ULN.

## Responsibilities Matrix

| Activity | GP / Primary Care | Specialist via Advice & Guidance | Specialist referral |
|---|---|---|---|
| Confirm diagnosis of menopause | ✓ | | |
| Assess severity of vasomotor symptoms | ✓ | | |
| Assess suitability for HRT and second line options | ✓ | | |
| Assess eligibility for fezolinetant | ✓ | | |
| Screen for contraindications | ✓ | | |
| Advice & Guidance for specialist recommendation | ✓ | | |
| Refer complex cases directly to specialist | ✓ | | |
| Arrange baseline LFTs | ✓ | | |
| Arrange baseline renal function assessment | ✓ | | |
| Assess complex liver disease or abnormal LFTs | | | ✓ |
| Assess significant renal impairment | | | ✓ |
| Assess current or previous breast cancer | | | ✓ |
| Assess oestrogen-dependent malignancy history | | | ✓ |

| | | | |
|---|---|---|---|
| Support benefit-risk assessment where evidence is limited | | ✓ | |
| Initiate fezolinetant post Advice & Guidance | ✓ | | |
| Provide patient counselling | ✓ | | |
| Arrange Month 1–3 LFT monitoring | ✓ | | |
| Review abnormal monitoring results | ✓ | | |
| Provide advice regarding abnormal monitoring results | | ✓ | |
| Manage routine adverse effects | ✓ | | |
| Provide advice regarding significant adverse effects | | ✓ | |
| Decide on treatment discontinuation in straightforward cases | ✓ | | |
| Support discontinuation decisions in complex cases | | ✓ | |
| Review treatment effectiveness at 8–12 weeks | ✓ | | |
| Undertake annual review | ✓ | | |
| Report adverse reactions via Yellow Card | ✓ | | |

# Document Control

**Document Title:** Fezolinetant Primary Care Pathway

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|---|---|
| Version | 1.0 |
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| Author | Dr Narmatha Kangeyan<br>Consultant Obstetrician & Gynaecologist<br>United Lincolnshire Teaching Hospitals NHS Trust |
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| Supersedes | New document |

## Version History

| Version | Date | Author | Summary of Changes |
|---|---|---|---|
| 0.1 | 14/07/2026 | Dr N Kangeyan | Initial draft |
| 0.9 | | _____ | Revised following stakeholder feedback |
| 1.0 | 10/09/2026 | Dr N Kangeyan | Approved version |

Accessibility checked. Contains tables which may not be accessible to screen readers.