

Ubrogепant (UBRELVY) Criteria for Use July 2025

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive ubrogепant.

- Concurrent therapy with a strong CYP3A4 inhibitor (e.g., ketoconazole, itraconazole, clarithromycin)
- Patient has uncontrolled hypertension
- Patient has a history of Raynaud’s phenomenon with ischemia (e.g., history of digital ulcers, tissue necrosis, or other critical ischemia)¹
- Concurrent therapy with a triptan agent once ubrogепant is initiated
- Concurrent therapy with another gepant prescribed for abortive treatment
- Pregnancy

Inclusion Criteria

The answers to **all** of the following must be fulfilled in order to meet criteria.

- Treatment initiated by a VA/VA Community Care neurologist or locally designated headache expert^{2,3}
- Diagnosis of migraine, with or without aura, per the International Classification of Headache Disorders (ICHD-3)
- Moderate to severe migraine intensity
- Currently receiving preventive therapy for migraine if indicated
- Contraindication⁴, intolerance, or lack of response to trial of two different triptans at a clinically effective dose.

Additional Inclusion Criteria

Select if applicable:

- If using a combination of a calcitonin gene related peptide (CGRP)-targeted monoclonal antibody for preventative therapy and ubrogепant for abortive therapy, patient has been evaluated and counseled on risks of concomitant therapy⁵

Footnotes

¹ Ubrogепant should be discontinued if signs or symptoms of Raynaud’s phenomenon develop. All patients with a history of Raynaud’s phenomenon should be monitored for and informed about the possibility of recurrence and worsening.

² A locally designated headache expert should be performing a comprehensive headache assessment including evaluation for medication overuse headache, other secondary headache types, adherence to prior headache therapies, and features that require urgent/emergent evaluation. Also, the patient’s headache history should

be reviewed to identify triggers, effective preventive treatment (if indicated), and nonpharmacologic interventions. A board certification in headache medicine is not required to meet this criterion.

³ Patients started on ubrogepant must have a scheduled blood pressure check 2-4 weeks after initiation of therapy

⁴ Vascular contraindications to all triptans include ischemic coronary artery disease, previous stroke or transient ischemic attack, peripheral vascular disease, or ischemic bowel disease. Other contraindications with triptans may be drug interaction related such as concurrent use of a MAO inhibitor.

⁵ Safety evidence of concomitant CGRP acting agents is limited. Patients may be prone to CGRP-related adverse events. CGRP is involved in many pathophysiologic pathways including vasodilation and GI motor-stimulation and prosecretory effects. Alternative therapies may benefit patients at high risk for adverse outcomes from this combination (like high risk for ischemic events, severe constipation, etc.).

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