Clinical Policy: Ubrogepant (Ubrelvy)
Reference Number: CP.PHAR.476
Effective Date: 06.01.20
Last Review Date: 08.20
Line of Business: Commercial, HIM, Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Ubrogepant (Ubrelvy™) is a calcitonin gene-related peptide (CGRP) receptor antagonist.

FDA Approved Indication(s)
Ubrelvy is indicated for the acute treatment of migraine with or without aura in adults.

Limitation(s) of use: Ubrelvy is not indicated for the preventive treatment of migraine.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Ubrelvy is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Migraines (must meet all):
      1. Diagnosis of migraine headaches;
      2. Age ≥ 18 years;
      3. Failure of at least TWO formulary 5HT1B/1D-agonist migraine medications (e.g., sumatriptan, rizatriptan, zolmitriptan) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
      4. For requests for monthly quantities > 1 box of 10 tablets per month, member meets all of the following (a, b, and c):
         a. Failure of TWO oral migraine prophylactic therapies from different therapeutic classes, each for 8 weeks, unless clinically significant adverse effects are experienced or all are contraindicated (see Appendix B);
         *Prior authorization may be required.
         b. Failure of a 3-month trial of ONE CGRP inhibitor* used for migraine prophylaxis, unless clinically significant adverse effects are experienced or all are contraindicated (see Appendix B);
         *Prior authorization may be required.
         c. Member is being treated by or in consultation with a neurologist, headache, or pain specialist;
      5. Ubrelvy is not prescribed concurrently with other CGRP inhibitors (e.g., Aimovig™, Ajovy™, Emgality™);
      6. Dose does not exceed 200 mg (2 tablets) per day and 8 days per month.

Approval duration: 6 months
B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Migraines (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. For dose increase requests to quantities > 1 box of 10 tablets per month, member meets all of the following (a, b, and c):
   a. Failure of at least TWO oral migraine prophylactic therapies from different therapeutic classes, each for 8 weeks, unless clinically significant adverse effects are experienced or all are contraindicated (see Appendix B);
      *Prior authorization may be required.
   b. Failure of a 3-month trial of ONE CGRP inhibitor* used for migraine prophylaxis, unless clinically significant adverse effects are experienced or all are contraindicated (see Appendix B);
      *Prior authorization may be required.
   c. Member is being treated by or in consultation with a neurologist, headache, or pain specialist;
4. Ubrelvy is not prescribed concurrently with other CGRP inhibitors (e.g., Aimovig™, Ajovy™, Emgality™);
5. If request is for a dose increase, new dose does not exceed 200 mg (2 tablets) per day and 8 days per month.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.  
   
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

<table>
<thead>
<tr>
<th>Abortive Migraine Therapy</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Triptans</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>naratriptan (Amerge®)</td>
<td>One tablet (1 or 2.5 mg) PO at onset; can be repeated in 4 hours</td>
<td>5 mg/day</td>
</tr>
<tr>
<td>almotriptan (Axert®)</td>
<td>6.25 to 12.5 mg PO QD May repeat dose in 2 hours</td>
<td>25 mg/day</td>
</tr>
<tr>
<td>frovatriptan (Frova®)</td>
<td>2.5 mg PO QD May repeat dose in 2 hours</td>
<td>7.5 mg/day</td>
</tr>
<tr>
<td>sumatriptan (Imitrex® nasal spray)</td>
<td>One spray (5 to 20 mg) at onset into one nostril; can be repeated in 2 hours</td>
<td>40 mg/day</td>
</tr>
<tr>
<td>sumatriptan (Imitrex®)</td>
<td>One tablet (25 to 100 mg) PO at onset; can be repeated in two hours</td>
<td>200 mg/day</td>
</tr>
<tr>
<td>rizatriptan (Maxalt®/Maxalt MLT®)</td>
<td>One tablet (5 or 10 mg) PO at onset of migraine headache; can be repeated in two hours</td>
<td>30 mg/day</td>
</tr>
<tr>
<td>eletriptan (Relpax®)</td>
<td>20 or 40 mg PO QD May repeat dose in 2 hours</td>
<td>40 mg/dose 80 mg/day</td>
</tr>
<tr>
<td>zolmitriptan (Zomig®/Zomig® ZMT)</td>
<td>1.25 or 2.5 mg PO QD May repeat dose in 2 hours</td>
<td>5 mg/dose 10 mg/day</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prophylactic Migraine Therapy</th>
<th>Dosing Regimen</th>
<th>Level of Evidence*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Antiepileptic Drugs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>divalproex sodium (Depakote®)</td>
<td>500 to 1,000 mg/day PO</td>
<td>Level A (AAN; AHS)</td>
</tr>
<tr>
<td>divalproex sodium ER (Depakote® ER)</td>
<td>500 to 1,000 mg/day PO</td>
<td>Level A (AAN; AHS)</td>
</tr>
<tr>
<td>topiramate (Topamax®)</td>
<td>100 mg/day PO</td>
<td>Level A (AAN; AHS)</td>
</tr>
<tr>
<td><strong>Beta-Blockers</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>metoprolol (Lopressor®)</td>
<td>200 mg/day PO</td>
<td>Level A (AAN; AHS)</td>
</tr>
<tr>
<td>propranolol (Inderal®)</td>
<td>80 to 240 mg/day PO</td>
<td>Level A (AAN; AHS)</td>
</tr>
<tr>
<td>timolol (Blocadren®)</td>
<td>20 to 30 mg/day PO</td>
<td>Level A (AAN; AHS)</td>
</tr>
<tr>
<td>atenolol (Tenormin®)</td>
<td>100 mg/day PO</td>
<td>Level B (AAN; AHS)</td>
</tr>
<tr>
<td>nadolol (Corgard®)</td>
<td>80 to 240 mg/day PO</td>
<td>Level B (AAN; AHS)</td>
</tr>
</tbody>
</table>
Serotonin Reuptake Inhibitors

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dosage Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>venlafaxine XR (Effexor XR®)</td>
<td>150 mg/day PO Level B (AAN; AHS)</td>
</tr>
</tbody>
</table>

Tricyclic Antidepressants

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dosage Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>amitriptyline (Elavil®)</td>
<td>30 to 150 mg/day PO Level B (AAN; AHS)</td>
</tr>
</tbody>
</table>

CGRP Inhibitors**

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dosage Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aimovig (erenumab)</td>
<td>70 mg SC once a month; may be increased to 140 mg SC once a month 140 mg/month</td>
</tr>
<tr>
<td>Ajovy (fremanezumab)</td>
<td>225 mg SC once a month or 675 mg SC every 3 months 225 mg/month or 675 mg/3 months</td>
</tr>
<tr>
<td>Emgality (galcanezumab)</td>
<td>240 mg SC as a single loading dose, followed by 120 mg SC once a month 120 mg/month</td>
</tr>
</tbody>
</table>

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.


**FDA approved.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): concomitant use with strong CYP3A4 inhibitors
- Boxed warning(s): none reported

Appendix D: General Information

- The AAN recommends that prophylactic migraine medications should be considered if the patient experiences 2 or more attacks per month that produce aggregate disability of 3 or more days/month.
- The AAN and the National Headache Foundation recommend that prophylactic migraine medications should be considered if one or more of the following are present: greater than 2 migraine headaches per week; migraines cause significant impairment in daily routine even with abortive treatment; contraindication to, adverse effects, overuse or failure of abortive migraine medications, presence of uncommon migraine condition (e.g., basilar migraine); or patient requesting prophylactic therapy.

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Migraines</td>
<td>50 or 100 mg PO, as needed. If needed, a second dose may be administered at least 2 hours after the initial dose. The maximum dose in a 24-hour period is 200 mg.</td>
<td>200 mg/day</td>
</tr>
</tbody>
</table>

VI. Product Availability

Tablets (package size 10, 12, 30): 50 mg, 100 mg
VII. References


<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy created</td>
<td>02.04.20</td>
<td>05.20</td>
</tr>
<tr>
<td>Revised requirement ‘for monthly quantities &gt; 1 box of 6 tablets per month’ to 10 tablets per month as this is the smallest available package size. Updated Section VI to remove the 6 and 8 tablet package sizes.</td>
<td>06.08.20</td>
<td>08.20</td>
</tr>
</tbody>
</table>

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

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discrepancy between the effective date of this clinical policy and any applicable legal or
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members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage
provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please
refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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