COUPE HEALTH

PHARMACY UTILIZATION MANAGEMENT (UM) PROGRAM CRITERIA ACTIVITY

Provider Notification

Policies Effective: August 1, 2022 Notification Posted: June 15,2022

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Revisions are effective the first of the month following a 45-day notification and comment period.

UM PROGRAM CRITERIA REVISED			
Nurtec (Rimegepant)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy
Nurtec	1. Updated requirement for 3 preventative treatments in patients with 4 or more migraines per month to being concurrently managed on a migraine preventative treatment. 2. Updated concurrent use of acute treatment to include Reyvow. 3. AWP Price current as of 6-8-22		

Prior Authorization Approval Criteria

Nurtec (rimegepant)

Generic name: Rimegepant
Brand name: Nurtec
Medispan GPI 6770106070**** MONY
Medication class: calcitonin gene-related peptide receptor (CGRP) antagonists
FDA-approved uses: **Acute treatment of migraine**
Preventative treatment of episodic migraine in adults

Usual dose range:
Acute Treatment 75mg as a single dose (max dose – 75mg/day)
Preventative Treatment 75mg every other day

Duration of Authorization:
Initial: 3 months
Ongoing: 12 months

Estimated Cost: $1103.14 per box of 8 tablets (AWP)

Criteria for use for Acute Treatment

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be prescribed by, or in consultation with a neurologist, pain specialist or headache disorder specialist.
- Patient must be 18 years or older
- Patient must be clinically diagnosed with migraine
- Patient has failure, contraindication, or intolerance to 2 preferred generic oral triptans
    - Sumatriptan (Imitrex)
    - Rizatriptan (Maxalt)
    - Zolmitriptan (Zomig)
    - Naratriptan (Amerge)
    - Eletriptan (Relpax)
- In patients with 4 or more migraines per month (per AAFP guidelines), patient is required to be concurrently managed on a migraine preventative therapy, unless otherwise clinically inappropriate to use a preventative therapy. Generic preferred agents include:
    - Amitriptyline (Elavil)
    - Beta-Blockers (Metoprolol, Propranolol, Nadolol)
    - Botox (may require specialty drug review with fail first requirements)
    - CGRP approved for preventative treatment (may require drug review with fail first requirements)
    - Divalproex Sodium (Depakote, Depakote ER)
    - Sodium Valproate (Depakene, Depacon)
    - Topiramate (Topamax)
    - Gabapentin (Neurontin)
    - Venlafaxine (Effexor)
    - Verapamil

  Certain preventative therapies may require have additional step-therapy, clinical review, and quantity limit requirements.
- Patient is not concomitantly using another CGRP antagonist (Ubrelvy) or 5-HT 1F receptor agonist (Reyvow) indicated for the treatment of breakthrough migraines.
- Quantity limit of 10 tablets/month.

Criteria for use for Preventative Treatment

- Plan excludes use of Nurtec for migraine prevention and only covers a maximum of 8 tablets per month for acute migraine treatment.

Criteria continuation of therapy

- Patient is tolerating and responding to medication and there continues to be a medical need for the medication.
- Chart notes evaluating the safety and efficacy from within the prior 12 months are required for reauthorization.

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- Patients under the age of 18 - safety and effectiveness in pediatric patients have not been established.

Not approved if:

- Patient does not meet any of the above criteria.

- Patient has a contraindication to treatment.
- Used for migraine prevention. Authorization limited to acute migraine treatment only.
- Patients with severe hepatic impairment (Child-Pugh class C) – manufacturer notes to avoid use
- Patients with CrCl <15 mL/minute or on dialysis – manufacturer notes to avoid use

Special Considerations:

- The maximum dose in a 24-hour period is 75mg.
- The safety of treating more than 15 migraines in a 30-day period has not been established

References:

1. Nurtec ODT (rimegepant) [prescribing information]. New Haven, CT: Biohaven Pharmaceuticals Inc; May 2021.
2. Ha H, Gonzalez A. Migraine headache prophylaxis. AFP. 2019;99(1):17-24.

MedOne P&T Committee approval: Date: 2-27-2020

Adopted:	2-27-2020
Revised:	5-28-21 9-3-21 12-7-21 2-2-22 2-17-22 6-8-22

Updates:

5-28-21
1. Nurtec for preventative treatment

9-3-21
1. Added requirement for <15 migraines per month
2. Added fail first requirement preferred migraine prevention treatments
3. Added restriction for concurrent use with other CGRP antagonists

12-7-21
1. Updated sentence
    - Patient is not concomitantly taking another CGRP antagonist (Ubrelvy)
        - to
    - Patient is not concomitantly using another CGRP antagonist (Ubrelvy) indicated for the treatment of breakthrough migraines.
2. Patient is not concomitantly using another CGRP antagonist or inhibitor (Aimovig, Ajovy, Emgality, Vyepti) for routine prophylaxis due to lack of evidence supporting efficacy of this drug-drug duplication

2-2-22
1. Updated fail first criteria from 3 preferred generic triptans to 2 preferred generic triptans

2-17-22
1. Removed concomitant use of preventative CGRP restriction
2. Updated preventative treatment requirements to 4 or more days per month per AAFT guidelines
3. Added preventative CGRP's to list of preventative treatments in patients with 4 or more migraines per month

6-8-22
1. Updated requirement for 3 preventative treatments in patients with 4 or more migraines per month to being concurrently managed on a migraine preventative treatment.
2. Updated concurrent use of acute treatment to include Reyvow.
3. AWP Price current as of 6-8-22

Effective Date (most recent revisions): 8-1-22

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NEW UM PROGRAM CRITERIA			
Qelbree (viloxazine)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy

Prior Authorization Approval Criteria

Qelbree (viloxazine)

Generic name: viloxazine
Brand name: Qelbree
Medispan GPI: MON
Medication class: Selective Norepinephrine Reuptake Inhibitor
FDA-approved uses: Treatment of attention deficit hyperactivity disorder (ADHD)

Usual dose range:

Adults	Initial: 200mg once daily	Maintenance: May increase to a maximum of 600mg/day
Pediatric 6-11 years old	Initial: 100mg once daily	Maintenance: May increase to a maximum of 400mg/day
Pediatric 12-17 years old	Initial: 200mg once daily	Maintenance: May increase to a maximum of 400mg/day

Duration of Authorization:

Initial: 4 months
Ongoing: 1 year

Criteria for use for ADHD

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Chart notes must be submitted from a recent encounter (within the past 12 months).
- Must be 6 years or older
- For adult patients - Provider must submit a diagnostic assessment for new starts. This is required for all new diagnosis in adults. Accepted criteria include a DSM IV/V criteria checklist, ASRS, CAARS, and the Conners adult ADHD rating scale.
    - This requirement is waived if patient has a pre-existing diagnosis of ADD/ADHD
- Within the clinical documentation provided, the provider assessment must support a diagnosis of Attention Deficit Disorder or Attention Deficit Hyperactivity Disorder consistent with DSM IV / V diagnostic criteria.
    - If assessment does not clearly confirm a diagnosis consistent with DSM IV/V criteria, a objective assessment (DSM checklist, Vanderbilt, etc.) may be required to be submitted for authorization.
- The daily cumulative dose of all stimulants cannot exceed the equivalent dose FDA approved maximum of any individual agent
- Furthermore, dose titration must be within FDA approved labeling guidelines
- Once daily formulation will only be approved for 1 dose per day
- Patient has failure, contraindication, or intolerance to at least TWO preferred non-stimulant generic medications
    - Atomoxetine
    - Guanfacine
    - Clonidine

Criteria continuation of therapy

- Patient is tolerating and responding to medication and there continues to be a medical need for the medication.
- Updated chart notes from an encounter within the last 12 months required for all annual reviews.

Contraindications:

- Hypersensitivity to any component of the formulation
- Concurrent use of monoamine oxidase inhibitor (MAOI), or within 14 days of the last MAOI dose
- Concomitant use of sensitive CYP1A2 substrates or CYP1A2 substrates with a narrow therapeutic range.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.

Special considerations:

- In patients with severe renal impairment (eGFR <30 mL/minute/1.73 m2); initial dose should be 100mg/day, and maximum dose should not exceed 200mg/day.
- Grandfather – use for FDA recognized conditions may be allowed with documentation the patient is currently stable and clinical documentation is supportive of patient meeting the clinical efficacy and tolerability of this treatment. Dose must be within FDA dosing limits on branded medications.
- Administer without regard to food; do not cut, chew, or crush capsule. Swallow capsules whole or open and sprinkle entire contents on teaspoonful of applesauce or pudding; consume entire mixture without chewing within 15 minutes for pudding or 2 hours for applesauce; do not store for future use.
- Viloxazine can increase heart rate and blood pressure. Prior to treatment with medications for attention-deficit hyperactivity disorder (ADHD), the American Heart Association and the American Academy of Pediatrics recommend that all children and adolescents diagnosed with ADHD have a thorough cardiovascular assessment, including patient and family health histories, determination of all medications used (prescribed and over-the-counter), and a physical examination focused on cardiovascular disease risk factors. An ECG is not mandatory but is reasonable to consider prior to stimulant medication therapy. Prompt evaluation and appropriate referral and testing, if warranted, should occur if any cardiac symptoms present.

References:

1. Qelbree (viloxazine) [prescribing information]. Rockville, MD: Supernus Pharmaceuticals Inc; April 2022.
2. Yu C, Garcia-Olivares J, Candler S, Schwabe S, Maletic V. New insights into the mechanism of action of viloxazine: serotonin and norepinephrine modulating properties. J Exp Pharmacol. 2020;12:285-300. doi:10.2147/JEP.S256586[PubMed 32943948]
3. Wolraich M, Brown L, Brown RT, et al: Subcommittee on Attention-Deficit/Hyperactivity Disorder; Steering Committee on Quality Improvement and Management. ADHD: Clinical practice guideline for the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder in children and adolescents. Pediatrics. 2011;128(5):1007-1022.[PubMed 22003063]

MedOne P&T Committee approval: Date: 5-31-2022

Adopted: 5-31-2022
Revised:

Updates:
Effective Date (most recent revisions): 8-1-22

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NEW UM PROGRAM CRITERIA			
Reyvow (lasminditan)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy

Prior Authorization Approval Criteria

Reyvow (lasminditan)

Generic name: Lasmindiatan
Brand name: Reyvow
Medispan GPI 67406540600320**** MONY
Medication class: Serotonin (5-HT) 1F receptor agonist
FDA-approved uses: **Acute treatment of migraine**

Usual dose range:
Acute Treatment 50, 100, 200mg as a single dose (not to exceed 1 dose/24 hours)

Duration of Authorization:
Initial: 3 months
Ongoing: 12 months

Estimated Cost: $846.72 per box of 8 tablets (AWP)

Criteria for use for Acute Treatment

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be prescribed by, or in consultation with a neurologist, pain specialist or headache disorder specialist.
- Patient must be 18 years or older
- Patient must be clinically diagnosed with migraine
- Patient has failure, contraindication, or intolerance to 2 preferred generic oral triptans
    - Sumatriptan (Imitrex)
    - Rizatriptan (Maxalt)
    - Zolmitriptan (Zomig)
    - Naratriptan (Amerge)
    - Eletriptan (Relpax)
- In patients with 4 or more migraines per month (per AAFP guidelines), patient is required to be concurrently managed on a migraine preventative therapy, unless otherwise clinically inappropriate to use a preventative therapy. Generic preferred agents include:
    - Amitriptyline (Elavil)
    - Beta-Blockers (Metoprolol, Propranolol, Nadolol)
    - Botox (may require specialty drug review with fail first requirements)
    - CGRP approved for preventative treatment (may require drug review with fail first requirements)
    - Divalproex Sodium (Depakote, Depakote ER)
    - Sodium Valproate (Depakene, Depacon)
    - Topiramate (Topamax)
    - Gabapentin (Neurontin)
    - Venlafaxine (Effexor)
    - Verapamil

  Certain preventative therapies may require have additional step-therapy, clinical review, and quantity limit requirements.

- Patient is not concomitantly using CGRP antagonist (Ubrelvy, Reyvow) indicated for the treatment of breakthrough migraines.
- Quantity limit of 8 tablets/month (available as 50mg and 100mg)

Criteria continuation of therapy

- Patient is tolerating and responding to medication and there continues to be a medical need for the medication.
- Chart notes evaluating the safety and efficacy from within the prior 12 months are required for reauthorization.

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- Patients under the age of 18 - safety and effectiveness in pediatric patients have not been established.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.

Special Considerations:

- The maximum dose in a 24-hour period is 200mg.
- The safety of treating more than 4 migraines in a 30-day period has not been established.
- Potentially life-threatening serotonin syndrome (SS) has occurred in patients receiving lasmiditan without any other drugs associated with SS. SS may also occur when used in combination with other serotonergic agents (eg, selective serotonin reuptake inhibitors, serotonin-norepinephrine reuptake inhibitors, triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, buspirone, St. John's wort, tryptophan) or agents that impair metabolism of serotonin (eg, monoamine oxidase inhibitors [MAOIs] intended to treat psychiatric disorders, other MAOIs [ie, linezolid and IV methylene blue]). Monitor patients closely for signs of SS, such as mental status changes (eg, agitation, hallucinations, delirium, coma), autonomic instability (eg, tachycardia, labile BP, diaphoresis), neuromuscular changes (eg, tremor, rigidity, myoclonus), GI symptoms (eg, nausea, vomiting, diarrhea), and/or seizures. Discontinue treatment (and any concomitant serotonergic agent) immediately if signs/symptoms arise.
- May cause CNS depression, which may impair physical or mental abilities and cause significant driving impairment. Patients should not engage in activities requiring mental alertness, such as driving or operating heavy machinery, for at least 8 hours after administration. Patients may be unable to assess their own driving competence; patients unable to abstain from activities requiring mental alertness for at least 8 hours should not take lasmiditan.

References:

3. Reyvow (lasmiditan) [prescribing information]. Indianapolis, IN: Lilly USA LLC; December 2021.
4. Nelson DL, Phebus LA, Johnson KW, et al. Preclinical pharmacological profile of the selective 5-HT1F receptor agonist lasmiditan. Cephalalgia. 2010;30(10):1159-1169. doi:10.1177/0333102410370873[PubMed 20855361]
5. Ailani J, Burch RC, Robbins MS; Board of Directors of the American Headache Society. The American Headache Society consensus statement: update on integrating new migraine treatments into clinical practice. Headache. 2021;61(7):1021-1039. doi:10.1111/head.14153[PubMed 34160823]
6. Ashina M, Vasudeva R, Jin L, et al. Onset of efficacy following oral treatment with lasmiditan for the acute treatment of migraine: integrated results from 2 randomized double-blind placebo-controlled phase 3 clinical studies. Headache. 2019;59(10):1788-1801. doi:10.1111/head.13636[PubMed 31529622]

MedOne P&T Committee approval: Date: 6-8-22

Adopted: 6-8-22
Revised:
Updates:
6-8-22 1. AWP Price current as of 6-8-22

Effective Date (most recent revisions): 8-1-22

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UM PROGRAM CRITERIA REVISED			
Ubrelvy (ubrogepant)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy
Ubrelvy	1. Updated requirement for 3 preventative treatments in patients with 4 or more migraines per month to being concurrently managed on a migraine preventative treatment. 2. Updated concurrent use of acute treatment to include Reyvow. 3. AWP Price current as of 6-8-22		

Prior Authorization Approval Criteria

Ubrelvy (ubrogepant)

Generic name: ubrogepant
Brand name: Ubrelvy
Medispan GPI 6770108000**** MONY
Medication class: calcitonin gene-related peptide receptor (CGRP) antagonists
FDA-approved uses: **Acute treatment of migraine**

Usual dose range:
Acute Treatment 50 to 100mg as a single dose; may repeat in ≥2 hours

Duration of Authorization:
Initial: 3 months
Ongoing: 12 months

Estimated Cost: $1124.56 per box of 10 tablets (AWP)

Criteria for use for Acute Treatment

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be prescribed by, or in consultation with a neurologist, pain specialist or headache disorder specialist.
- Patient must be 18 years or older
- Patient must be clinically diagnosed with migraine
- Patient has failure, contraindication, or intolerance to 2 preferred generic oral triptans
    - Sumatriptan (Imitrex)
    - Rizatriptan (Maxalt)
    - Zolmitriptan (Zomig)
    - Naratriptan (Amerge)
    - Eletriptan (Relpax)

- In patients with 4 or more migraines per month (per AAFP guidelines), patient is required to be concurrently managed on a migraine preventative therapy, unless otherwise clinically inappropriate to use a preventative therapy. Generic preferred agents include:
    - Amitriptyline (Elavil)
    - Beta-Blockers (Metoprolol, Propranolol, Nadolol)
    - Botox (may require specialty drug review with fail first requirements)
    - CGRP approved for preventative treatment (may require drug review with fail first requirements)
    - Divalproex Sodium (Depakote, Depakote ER)
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    - Gabapentin (Neurontin)
    - Venlafaxine (Effexor)
    - Verapamil

  Certain preventative therapies may require have additional step-therapy, clinical review, and quantity limit requirements.
- Patient is not concomitantly using another CGRP antagonist (Nurtec) or 5-HT 1F receptor agonist (Reyvow) indicated for the treatment of breakthrough migraines.
- Quantity limit of 10 tablets/month.

Criteria continuation of therapy

- Patient is tolerating and responding to medication and there continues to be a medical need for the medication.
- Chart notes evaluating the safety and efficacy from within the prior 12 months are required for reauthorization.

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- Patients under the age of 18 - safety and effectiveness in pediatric patients have not been established.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- For prophylactic use
- Patients with CrCl <15 mL/minute or on dialysis – manufacturer notes to avoid use

Special Considerations:

- The maximum dose in a 24-hour period is 200mg.
- The safety of treating more than 8 migraines in a 30-day period has not been established
- Patients with CrCl 15-29 mL/minute – 50mg as a single dose initially; max dose of 100mg/24 hours
- Patients with severe hepatic impairment (Child-Pugh class C) – 50mg as a single dose initially; max dose of 100mg/24 hours

References:

7. Ubrelvy (ubrogepant) [prescribing information]. Madison, NJ: Allergan USA Inc; March 2021.
8. Ha H, Gonzalez A. Migraine headache prophylaxis. AFP. 2019;99(1):17-24.

MedOne P&T Committee approval: Date: 12-23-2019

Adopted: 12-23-2019
Revised: 9-3-21
12-7-21

2-2-22
2-17-22
6-8-22

Updates:

9-3-21
1. Added requirement for <8 migraines per month
2. Added fail first requirement preferred migraine prevention treatments
3. Added restriction for concurrent use with other CGRP antagonists

12-7-21
1. Updated sentence
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    - Patient is not concomitantly using another CGRP antagonist (Ubrelvy) indicated for the treatment of breakthrough migraines.
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