COUPE HEALTH

PHARMACY UTILIZATION MANAGEMENT (UM) PROGRAM CRITERIA ACTIVITY

Provider Notification

Policies Effective: 2/1/2023 Notification Posted: 12/16/2022

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

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

Prior Authorization Approval Criteria

Ingrezza (valbenazine)

Generic name: valbenazine
Brand name: Ingrezza
Medispan GPI: 623800802001** MON
Medication class: Central Nervous System Agent
FDA-approved uses: **Tardive Dyskinesia (TD)**

Usual dose range:
Tardive Dyskinesia Initial: 40mg daily for 1 week Maintenance: 80mg daily

Duration of Authorization:
Initial: 4 months
Ongoing: 12 months

Estimated Cost: $117,121.20 per year (80mg daily) - AWP

Criteria for use for indication tardive dyskinesia (TD)

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be 18 years of age or older.
- Grandfather criteria allowed
    - Please see policy and procedure "*14 – Grandfather Status Authorization*" for additional information.
- Patient is clinically diagnosed with moderate to severe antipsychotic-induced tardive dyskinesia (moderate or severe TD as indicated by a score of 3 or 4 on item 8 (severity of abnormal movement overall) of the Abnormal Involuntary Movement Scale (AIMS).
    - Documentation of the member's current AIMS score must be included.
- Must be prescribed by, or in consultation with a board-certified psychologist.
- Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication, -OR- patient not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication.
    - Patient would be considered not a candidate for dose reduction as defined by previous failure of reduction due to exacerbation of disease state; or provider submits documentation that reduction or discontinuation would put the patient at risk for undo harm.
- Patient has failure, contraindication, or intolerance to at least TWO generic trials first:
    - Clonazepam
    - Amantadine
    - Tetrabenazine
- Patient is not at a significant risk for suicidal or violent behavior and does not have unstable psychiatric symptoms.

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 or other clinical documentation confirming efficacy and tolerability of the requested treatment will be required for all renewal reviews. Submitted clinical documentation must be from an encounter after the start date of the current approval.
    - Efficacy defined as TD symptoms have improved due to Ingrezza use as evidenced by AIMS score (items 1-7) showing reduction of score from baseline.
- Patient demonstrates adequate compliance as defined as an MPR >80%.

Contraindications:

- History of hypersensitivity to any of the product ingredients
- Patient is actively suicidal
- Concomitant use of an MAOI or within 14 days of discontinuing therapy with an MAOI
- Concomitant use of reserpine or within 20 days of reserpine discontinuation
- Depression, untreated or inadequately-treated
- Hepatic impairment

Not approved if:

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

Special Considerations:

- In patients with impaired hepatic function (Child-Pugh class B or C) – 40mg once daily.
- May cause CNS depression, which may impair physical or mental abilities; patients must be cautioned about performing tasks that require mental alertness (eg, operating machinery or driving).
- Vesicular monoamine transport inhibitors have been associated with depression and suicidal thoughts and behavior.
- Cases of parkinson-like symptoms (eg, falls, gait disturbances, tremor, drooling, hypokinesia), some severe requiring hospitalization, have been reported. Onset of severe symptoms occurs most commonly within 2 weeks of the start of therapy or a dose increase; may resolve with discontinuation of therapy. Reduce dose or discontinue treatment in patients who develop clinically significant parkinson-like signs or symptoms.
- May prolong the QT interval; use caution when used concomitantly with a strong CYP2D6 or CYP3A4 inhibitor or in a poor CYP2D6 metabolizer, dose reduction may be necessary. Avoid use in patients with congenital long QT syndrome or arrhythmias associated with prolonged QT interval. For patients at risk of prolonged QT interval, perform EKG before increasing the dosage.
- Use with caution in patients with moderate or severe hepatic impairment; use reduced dose.

References:

1. Ingrezza (valbenazine) [prescribing information]. San Diego, CA: Neurocrine Biosciences Inc; August 2022.
2. McIntyre RS, Calabrese JR, Nierenberg AA, et al. The effects of valbenazine on tardive dyskinesia in patients with a primary mood disorder. J Affect Disord. 2019;246:217-223.[PubMed 30583148]10.1016/j.jad.2018.12.023

MedOne Clinical Review Subcommittee approval: Date: 12-14-22

Initial adoption:	12-14-22
Revised:	12-14-22
12-14-22	1. Pricing updated based off of AWP (12-12-22)
Effective Date (most recent revisions):	2-1-23

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

UM PROGRAM CRITERIA REVISED			
Absorica; Absorica LD (isotretinoin)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy
Absorica	1. References 2-7 added to documentation		

Prior Authorization Approval Criteria

Absorica; Absorica LD
(isotretinoin)

Generic name: Isotretinoin
Brand name: Amnesteem; Claravis; Myorisan; Zenatane
Medication class: First generation Retinoid
FDA-approved uses: Severe recalcitrant nodular acne

Usual dose range:

Severe recalcitrant nodular acne	Initial: 0.5 mg/kg/day in 2 divided doses for 1 month	Maintenance: Increase to 1 mg/kg/day in 2 divided doses as tolerated. Continue until a total cumulative dose of 120 to 150 mg/kg is reached

Duration of Authorization:

Initial:	5 months (or until a maximum cumulative dose of 150mg/kg has been reached)
Reauthorization	Member must be have been off oral isotretinoin therapy for at least 2 months (8 weeks) Persistent or recurring severe recalcitrant nodular acne is still occurring Maximum of only one reauthorization will be issued.

Estimated Cost:

Criteria for use for Indication severe recalcitrant nodular acne

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan
- Member is 12 years or older
- Medication must be prescribed by or in consultation with a dermatologist
- History of failure, contraindication, or intolerance to an adequate trial on the following conventional therapy regimens:
    - Topical retinoid or retinoid-like agent [Retin-A/Retin-A Micro (tretinoin), tazarotene (Arazlo)]
    - Oral antibiotic [eg, Ery-Tab (erythromycin), Biaxin (clarithromycin), Minocin (minocycline)]
    - Topical antibiotic with or without benzoyl peroxide [eg, Cleocin-T (clindamycin), erythromycin, BenzaClin (benzoyl peroxide/clindamycin), Benzamycin (benzoyl peroxide/erythromycin)]

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.
- Patient has not reached a maximum cumulative dose of 150mg/kg.
- Patient must demonstrate a minimum of 80% compliance with prescribed therapy during course of treatment.
- Plan requires 2 months (8 weeks) before a second treatment course may be considered.

Contraindications:

- History of hypersensitivity to any of the product ingredients
- Patients that are pregnant. Patients of childbearing potential must be able to comply with the guidelines of the iPLEDGE™ pregnancy prevention program.

Not approved if:

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

Special Considerations:

- Once daily dosing is not recommended
- Isotretinoin must only be prescribed by health care providers who are registered and activated with the iPLEDGE program. Isotretinoin must only be dispensed by a pharmacy registered and activated with iPLEDGE and must only be dispensed to patients who are registered and meet all the requirements of iPLEDGE. Registered and activated pharmacies must receive isotretinoin only from wholesalers registered with iPLEDGE.
- Avoid prolonged exposure to UV rays or sunlight.
- Should be taken with food
- Use should be avoided while breastfeeding
- In adult patients with very severe disease (scarring, trunk involvement) may increase dosage to 2 mg/kg/day in divided doses
- Prior to prescribing, perform fasting lipid profile and liver function tests

References:

1. Amnesteem (isotretinoin) [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals Inc; August 2018.
2. Claravis (isotretinoin) [prescribing information]. Pomona, NY: Barr Laboratories Inc; April 2018.
3. Sotret (isotretinoin) [prescribing information]. Jacksonville, FL: Ranbaxy Laboratories Inc; August 2005.
4. Myorisan (isotretinoin) [prescribing information]. Lake Forest, IL: VersaPharm Inc; December 2018.
5. Zenatane (isotretinoin) [prescribing information]. Princeton, NJ: Dr. Reddy's Laboratories Inc; January 2019.
6. Topical preparations for the treatment of mild-to-moderate acne vulgaris: systematic review and network meta-analysis. B. Stuart,E. Maund et al. Britrish Journal of Dermatology. Volume 185, Issue 3. September 2021, Pages 512-525. https://doi.org/10.1111/bjd.20080
7. Acne Vulgaris. Zaenglein AL. N Engl J Med. 2018;379(14):1343-1352. doi:10.1056/NEJMcp1702493
8. Acne Treatment. Raj Chovatiya, MD, PhD. JAMA. 2021;326(20):2087. doi:10.1001/jama.2021.16599
9. Dermatology: how to manage acne vulgaris. Alexander KC Leung, Benjamin Barankin, Joseph M Lam, Kin Fon Leong, and Kam Lun. Drugs Context. 2021; 10: 2021-8-6. doi: 10.7573/dic.2021-8-6
10. Guidelines of care for the management of acne vulgaris. Zaenglein AL, Pathy AL, Schlosser BJ, et al. J Am Acad Dermatol. 2020 Jun;82(6):1576]. doi:10.1016/j.jaad.2015.12.037
11. Dermatology: how to manage acne vulgaris. Alexander KC Leung, Benjamin Barankin, Joseph M Lam, Kin Fon Leong, and Kam Lun Hon. Drugs Context. 2021; 10: 2021-8-6. doi: 10.7573/dic.2021-8-6
12. Management of Acne Vulgaris: A Review. Dawn Z. Eichenfield, MD, PhD; Jessica Sprague, MD; Lawrence F. Eichenfield, MD. JAMA. 2021;326(20):2055-2067. doi:10.1001/jama.2021.17633

MedOne P&T Committee approval: Date: 1-1-17

Initial adoption: 1-1-17
Revised: 12-14-22
12-14-22 1. References 7-12 added to documentation
Effective Date (most recent revisions): 2-1-2023

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

Please note:
This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions. Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.
This clinical policy has been developed by 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 MedOne Pharmacy Benefits, or any of such health plan's affiliates, as applicable.

UM PROGRAM CRITERIA REVISED			
Amnesteem; Claravis; Myorisan; Zenatane (isotretinoin)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy
Amnesteem	1. References 7-12 added to documentation		

Prior Authorization Approval Criteria

Amnesteem; Claravis; Myorisan; Zenatane (isotretinoin)

Generic name: Isotretinoin
Brand name: Amnesteem; Claravis; Myorisan; Zenatane
Medication class: First generation Retinoid
FDA-approved uses: Severe recalcitrant nodular acne

Usual dose range:

Severe recalcitrant nodular acne	Initial: 0.5 mg/kg/day in 2 divided doses for 1 month	Maintenance: Increase to 1 mg/kg/day in 2 divided doses as tolerated. Continue

until a total cumulative dose of 120 to 150 mg/kg is reached

Duration of Authorization:

Initial:	5 months (or until a maximum cumulative dose of 150mg/kg has been reached)
Reauthorization	Member must be have been off oral isotretinoin therapy for at least 2 months (8 weeks) Persistent or recurring severe recalcitrant nodular acne is still occurring Maximum of only one reauthorization will be issued.

Estimated Cost:

Criteria for use for Indication severe recalcitrant nodular acne

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan
- Member is 12 years or older
- Medication must be prescribed by or in consultation with a dermatologist
- History of failure, contraindication, or intolerance to an adequate trial on the following conventional therapy regimens:
    - Topical retinoid or retinoid-like agent [Retin-A/Retin-A Micro (tretinoin), tazarotene (Arazlo)]
    - Oral antibiotic [eg, Ery-Tab (erythromycin), Biaxin (clarithromycin), Minocin (minocycline)]
    - Topical antibiotic with or without benzoyl peroxide [eg, Cleocin-T (clindamycin), erythromycin, BenzaClin (benzoyl peroxide/clindamycin), Benzamycin (benzoyl peroxide/erythromycin)]

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.
- Patient has not reached a maximum cumulative dose of 150mg/kg.
- Patient must demonstrate a minimum of 80% compliance with prescribed therapy during course of treatment.
- Plan requires 2 months (8 weeks) before a second treatment course may be considered.

Contraindications:

- History of hypersensitivity to any of the product ingredients
- Patients that are pregnant. Patients of childbearing potential must be able to comply with the guidelines of the iPLEDGE™ pregnancy prevention program.

Not approved if:

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

Special Considerations:

- Once daily dosing is not recommended

- Isotretinoin must only be prescribed by health care providers who are registered and activated with the iPLEDGE program. Isotretinoin must only be dispensed by a pharmacy registered and activated with iPLEDGE and must only be dispensed to patients who are registered and meet all the requirements of iPLEDGE. Registered and activated pharmacies must receive isotretinoin only from wholesalers registered with iPLEDGE.
- Avoid prolonged exposure to UV rays or sunlight.
- Should be taken with food
- Use should be avoided while breastfeeding
- In adult patients with very severe disease (scarring, trunk involvement) may increase dosage to 2 mg/kg/day in divided doses
- Prior to prescribing, perform fasting lipid profile and liver function tests

References:

1. Amnesteem (isotretinoin) [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals Inc; August 2018.
2. Claravis (isotretinoin) [prescribing information]. Pomona, NY: Barr Laboratories Inc; April 2018.
3. Sotret (isotretinoin) [prescribing information]. Jacksonville, FL: Ranbaxy Laboratories Inc; August 2005.
4. Myorisan (isotretinoin) [prescribing information]. Lake Forest, IL: VersaPharm Inc; December 2018.
5. Zenatane (isotretinoin) [prescribing information]. Princeton, NJ: Dr. Reddy's Laboratories Inc; January 2019.
6. Topical preparations for the treatment of mild-to-moderate acne vulgaris: systematic review and network meta-analysis. B. Stuart,E. Maund et al. Britrish Journal of Dermatology. Volume 185, Issue 3. September 2021, Pages 512-525. https://doi.org/10.1111/bjd.20080
7. Acne Vulgaris. Zaenglein AL. N Engl J Med. 2018;379(14):1343-1352. doi:10.1056/NEJMcp1702493
8. Acne Treatment. Raj Chovatiya, MD, PhD. JAMA. 2021;326(20):2087. doi:10.1001/jama.2021.16599
9. Dermatology: how to manage acne vulgaris. Alexander KC Leung, Benjamin Barankin, Joseph M Lam, Kin Fon Leong, and Kam Lun. Drugs Context. 2021; 10: 2021-8-6. doi: 10.7573/dic.2021-8-6
10. Guidelines of care for the management of acne vulgaris. Zaenglein AL, Pathy AL, Schlosser BJ, et al. J Am Acad Dermatol. 2020 Jun;82(6):1576]. doi:10.1016/j.jaad.2015.12.037
11. Dermatology: how to manage acne vulgaris. Alexander KC Leung, Benjamin Barankin, Joseph M Lam, Kin Fon Leong, and Kam Lun Hon. Drugs Context. 2021; 10: 2021-8-6. doi: 10.7573/dic.2021-8-6
12. Management of Acne Vulgaris: A Review. Dawn Z. Eichenfield, MD, PhD; Jessica Sprague, MD; Lawrence F. Eichenfield, MD. JAMA. 2021;326(20):2055-2067. doi:10.1001/jama.2021.17633

MedOne P&T Committee approval: Date: 1-1-17

Initial adoption: 1-1-17
Revised: 12-14-22
12-14-22 1. References 7-12 added to documentation
Effective Date (most recent revisions): 2-1-2023

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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 MedOne Pharmacy Benefits, or any of such health plan's affiliates, as applicable.

UM PROGRAM CRITERIA REVISED			
Aimovig (erenumab)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy
Aimovig	1. Added pregabalin and nortriptyline to list of preferred generic preventative medications		

Prior Authorization Approval Criteria

Aimovig (erenumab)

Generic name: erenumab
Brand name: Aimovig
Medispan GPI 6770108000**** MONY
Medication class: Calcitonin Gene-Related Peptide Receptor (CGRP) Antagonists / Monoclonal Antibody
FDA-approved uses: **Preventative treatment of chronic migraine in adults**

Usual dose range:
Chronic Migraine Initial: 70mg once monthly Maintenance: 70 to 140mg once monthly

Duration of Authorization:
Initial: 6 months
Ongoing: 12 months

Estimated Cost: $9741/year AWP (12 injections of either 70mg or 140mg)

Criteria for use for chronic migraine

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Grandfather criteria allowed
  - *Please see policy and procedure "14 – Grandfather Status Authorization" for additional information.*
- 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 chronic migraine, as defined as symptoms lasting longer than 3 months.
- Patient must experience no less than 4 migraine days per month.
- Patient has failure, contraindication, or intolerance to 3 preferred generic preventative migraine therapies:
  - Amitriptyline (Elavil)
  - Beta-Blockers (Metoprolol, Propranolol, Nadolol)
  - Botox (may require specialty drug review with fail first requirements)
  - Divalproex Sodium (Depakote, Depakote ER)
  - Sodium Valproate (Depakene, Depacon)
  - Topiramate (Topamax)
  - Gabapentin (Neurontin

- Pregabalin (Lyrica)
- Nortriptyline (Pamelor)
- Venlafaxine (Effexor)
- Verapamil

- Patient is not concomitantly taking another CGRP antagonist or inhibitor for routine prophylaxis (Ajovy, Emgality, Qulipta, Vyepti).

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, as defined by a 50% reduction in average migraine days over the previous 3 months.

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:

- Administer in the abdomen, thigh, or upper arm subcutaneously
- Patients should be monitored for severe constipation, particularly patients with concurrent use of medications associated with decreased GI motility.
- Development of hypertension and worsening of pre-existing hypertension has been reported with the use of Aimovig, patients with pre-existing or risk factors for hypertension should be monitored, all patients should be counseled on the signs/symptoms of hypertension prior to first dose.

References:

1. Aimovig ® [package insert]. Thousand Oaks, CA: Amgen Inc; April 2020.

MedOne P&T Committee approval: Date: 12-14-2022

Adopted: 5-17-2018

Revised: 9-3-2021
12-7-2021
2-17-2022
3-31-2022
12-14-2022

Updates:

9-3-21
1. Added no concomitant treatment with other CGRP criteria
2. Added Botox to step criteria

12-7-21
1. Added Patient is not concomitantly taking another CGRP antagonist or inhibitor for routine prophylaxis (Ajovy, Emgality, Vyepti).
2. Added Patient is not concomitantly using acute CGRP antagonists (Nurtec or Ubrelvy) for acute treatment due to lack of evidence supporting efficacy of this drug-drug duplication

2-17-22
1. Removed concomitant use of acute CGRP restriction

3-31-22	1. Updated "Patient is not concomitantly taking with another CGRP antagonist or inhibitor (Ajovy, Emgality, Vyepti)" to ""Patient is not concomitantly taking with another CGRP antagonist or inhibitor (Ajovy, Emgality, Qulipta, Vyepti)" 2. Added definition of chronic migraine of symptoms lasting longer than 3 months. 3. Updated AWP to current 3-31-22 price
12-14-22	1. Added pregabalin and nortriptyline to list of preferred generic preventative medications

Effective Date (most recent revisions): 2-1-2023

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

UM PROGRAM CRITERIA REVISED			
Ajovy (frenmanezumab)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy
Ajovy	1. Added pregabalin and nortriptyline to list of preferred generic preventative medications		

Prior Authorization Approval Criteria

Ajovy (frenmanezumab)

Generic name: frenmanezumab
Brand name: Ajovy
Medispan GPI 6770203020**** MONY
Medication class: Calcitonin Gene-Related Peptide Receptor (CGRP) Antagonists / Monoclonal Antibody
FDA-approved uses: **Preventative treatment of chronic migraine in adults**

Usual dose range:
Indication #1 225mg monthly
-or-
675mg every 3 months

Duration of Authorization:
Initial: 6 months
Ongoing: 12 months

Estimated Cost: $9576/year AWP (12 injections of 225mg)

Criteria for use for migraine prevention

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Grandfather criteria allowed
  - *Please see policy and procedure "14 – Grandfather Status Authorization" for additional information.*
- 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 chronic migraine, as defined as symptoms lasting longer than 3 months.

- Patient must experience no less than 4 migraine days per month.
- Patient has failure, contraindication, or intolerance to 3 preferred generic preventative migraine therapies:
    - Amitriptyline (Elavil)
    - Nortriptyline (Pamelor)
    - Beta-Blockers (Metoprolol, Propranolol, Nadolol)
    - Botox (may require specialty drug review with fail first requirements)
    - Divalproex Sodium (Depakote, Depakote ER)
    - Sodium Valproate (Depakene, Depacon)
    - Topiramate (Topamax)
    - Gabapentin (Neurontin)
    - Pregabalin (Lyrica)
    - Venlafaxine (Effexor)
    - Verapamil (Verelan, Verelan PM, Calan SR)
- Patient has failure, contraindication, or intolerance to both Aimovig and Emgality.
- Patient is not concomitantly taking another CGRP antagonist or inhibitor for routine prophylaxis (Aimovig, Emgality, Qulipta, Vyepti).

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, as defined by a 50% reduction in average migraine days over the previous 3 months.

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:

- Administer in the abdomen, thigh, or upper arm subcutaneously.
- Some dosage forms may contain polysorbate 80 (also known as Tweens). Hypersensitivity reactions, usually a delayed reaction, have been reported following exposure to pharmaceutical products containing polysorbate 80 in certain individuals.

References:

1. Ajovy (fremanezumab-vfrm) [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA Inc; May 2021.
2. Ha H, Gonzalez A. Migraine headache prophylaxis. AFP. 2019;99(1):17-24.

MedOne P&T Committee approval: Date: 12-14-2022

Adopted: 9-14-2018

Revised: 9-3-2021
12-7-2021
2-17-2022
3-31-21
12-14-2022

Updates:

9-3-21	1. Added step therapy with Aimovig and Emgality 2. Added no concomitant treatment with other CGRP criteria 3. Added Botox to step criteria
12-7-21	1. Added Patient is not concomitantly taking another CGRP antagonist or inhibitor for routine prophylaxis (Aimovig, Emgality, Vyepti). 2. Added Patient is not concomitantly using acute CGRP antagonists (Nurtec or Ubrelvy) for acute treatment due to lack of evidence supporting efficacy of this drug-drug duplication
2-17-22	1. Removed concomitant use of acute CGRP restriction
3-31-22	1. Updated "Patient is not concomitantly taking with another CGRP antagonist or inhibitor (Ajovy, Emgality, Vyepti)" to ""Patient is not concomitantly taking with another CGRP antagonist or inhibitor (Aimovig, Emgality, Qulipta, Vyepti)" 2. Added definition of chronic migraine of symptoms lasting longer than 3 months. 3. Updated AWP to current 3-31-22 price
12-14-22	1. Added pregabalin and nortriptyline to list of preferred generic preventative medications

Effective Date (most recent revisions): 2-1-2023

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UM PROGRAM CRITERIA REVISED			
Emgality (galcanezumab)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy
Emgality	1. Added pregabalin and nortriptyline to list of preferred generic preventative medications		

Prior Authorization Approval Criteria

Emgality (galcanezumab)

Generic name: Galcanezumab
Brand name: Emgality
Medispan GPI 6770203530**** MONY
Medication class: Calcitonin Gene-Related Peptide Receptor (CGRP) Antagonists / Monoclonal Antibody
FDA-approved uses: **Preventative treatment of chronic migraine in adults**
Preventative treatment of cluster headache

Usual dose range:
Migraine Initial: 240mg once monthly Maintenance: 120mg once monthly
Cluster headache 300mg at the onset of the cluster period, then once monthly until the end of the cluster period

Duration of Authorization:
Initial: 6 months
Ongoing: 12 months

Estimated Cost: $10183.68/year AWP (13 injections of 120mg dose)

Criteria for use for migraine prevention

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Grandfather criteria allowed
    - *Please see policy and procedure "14 – Grandfather Status Authorization" for additional information.*
- 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 chronic migraine, as defined as symptoms lasting longer than 3 months.
- Request is for 120mg dose.
- Patient must experience no less than 4 migraine days per month.
- Patient has failure, contraindication, or intolerance to 3 preferred generic preventative migraine therapies:
    - Amitriptyline (Elavil)
    - Nortriptyline (Pamelor)
    - Beta-Blockers (Metoprolol, Propranolol, Nadolol)
    - Botox (may require specialty drug review with fail first requirements)
    - Divalproex Sodium (Depakote, Depakote ER)
    - Sodium Valproate (Depakene, Depacon)
    - Topiramate (Topamax)
    - Gabapentin (Neurontin)
    - Pregabalin (Lyrica)
    - Venlafaxine (Effexor)
    - Verapamil
- Patient is not concomitantly taking another CGRP antagonist or inhibitor for routine prophylaxis (Aimovig, Ajovy, Qulipta, Vyepti).

Criteria for use for cluster headache prevention

- 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 cluster headache.
- Request is for 100mg dose.
- Patient must experience at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months.
- Patient has failure, contraindication, or intolerance to generic verapamil.

Criteria continuation of therapy for migraine prevention

- 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, as defined by a 50% reduction in average migraine days over the previous 3 months.

Criteria continuation of therapy for cluster headache prevention

- 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, as defined by a reduction in reduction in headache frequency and/or intensity.

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:

- Administer in the abdomen, thigh, or upper arm subcutaneously
- Patients with history of stroke, intracranial or carotid aneurysm, intracranial hemorrhage, vasospastic angina or Raynaud disease, or clinical evidence of peripheral vascular disease were excluded from cluster headache clinical trials; use with caution in these patients.
- Some dosage forms may contain polysorbate 80 (also known as Tweens). Hypersensitivity reactions, usually a delayed reaction, have been reported following exposure to pharmaceutical products containing polysorbate 80 in certain individuals.

References:

1. Emgality (galcanezumab-gnlm) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; December 2019.

MedOne P&T Committee approval: Date: 12-15-2022

Adopted: 9-27-2018

Revised: 9-3-21
12-7-21
2-17-22
3-31-22
12-14-22

Updates:

9-3-21
1. Added no concomitant treatment with other CGRP criteria
2. Added Botox to step criteria
3. Added fail first to cluster headache – verapamil

12-7-21
1. Added Patient is not concomitantly taking another CGRP antagonist or inhibitor for routine prophylaxis (Aimovig, Ajovy, Vyepti).
2. Added Patient is not concomitantly using acute CGRP antagonists (Nurtec or Ubrelvy) for acute treatment due to lack of evidence supporting efficacy of this drug-drug duplication

2-17-22
1. Removed concomitant use of acute CGRP restriction

3-31-22
1. Updated "Patient is not concomitantly taking with another CGRP antagonist or inhibitor (Ajovy, Aimovig, Vyepti)" to ""Patient is not concomitantly taking with another CGRP antagonist or inhibitor (Aimovig, Ajovy, Qulipta, Vyepti)"
2. Added definition of chronic migraine of symptoms lasting longer than 3 months.
3. Updated AWP to current 3-31-22 price

12-14-22
1. Added pregabalin and nortriptyline to list of preferred generic preventative medications

Effective Date (most recent revisions): 2-1-2023

**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. Added pregabalin and nortriptyline to list of preferred generic preventative medications		

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)
    - Nortriptyline (Pamelor)
    - 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)

- Pregabalin (Lyrica)
- 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 8 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: 12-14-2022

Adopted:	2-27-2020
Revised:	5-28-21
	9-3-21
	12-7-21
	2-2-22
	2-17-22
	6-8-22
	12-14-2022

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
12-14-22	1. Added pregabalin and nortriptyline to list of preferred generic preventative medications

Effective Date (most recent revisions): 2-1-2023

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

UM PROGRAM CRITERIA REVISED			
Qulipta (atogepant)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy
Qulipta	1. Added pregabalin and nortriptyline to list of preferred generic preventative medications		

Prior Authorization Approval Criteria

Qulipta (atogepant)

Generic name: atogepant
Brand name: Qulipta
Medispan GPI 6770101000**** MON
Medication class: Calcitonin Gene-Related Peptide Receptor (CGRP) Antagonists
FDA-approved uses: **Preventative treatment of episodic migraine in adults**

Usual dose range:
Episodic Migraine 10, 30, or 60 mg once daily

Duration of Authorization:
Initial: 3 months

Ongoing: 12 months

Estimated Cost: $1189.20/30 days (AWP)

Criteria for use for migraine prevention

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Grandfather criteria allowed
    - *Please see policy and procedure "14 – Grandfather Status Authorization" for additional information.*
- 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 chronic migraine, as defined as symptoms lasting longer than 3 months.
- Patient must experience no less than 4 migraine days per month.
- Patient has failure, contraindication, or intolerance to 3 preferred generic preventative migraine therapies:
    - Amitriptyline (Elavil)
    - Nortriptyline (Pamelor)
    - Beta-Blockers (Metoprolol, Propranolol, Nadolol)
    - Botox (may require specialty drug review with fail first requirements)
    - Divalproex Sodium (Depakote, Depakote ER)
    - Sodium Valproate (Depakene, Depacon)
    - Topiramate (Topamax)
    - Gabapentin (Neurontin)
    - Pregabalin (Lyrica)
    - Venlafaxine (Effexor)
    - Verapamil
- Patient has failure, contraindication, or intolerance to both Aimovig -AND- Emgality, -OR- documented needle phobia (ICD-10 of F40.231 documented on chart -OR- confirmed previous injections with adverse outcome identified in claims history).
- Patient is not concomitantly taking another CGRP antagonist or inhibitor for routine prophylaxis (Aimovig, Ajovy, Emgality, Vyepti).

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, as defined by a 50% reduction in average migraine days over the previous 3 months.

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:

- For patients with altered kidney function
    - CrCl <30mL/min – 10mg daily

- ESRD on dialysis – 10mg daily, administer after dialysis on dialysis days
- For patient with impaired hepatic function
  - Severe impairment (Child-Pugh class C) – use is not recommended.

References:

1. Qulipta (atogepant) [prescribing information]. North Chicago, IL: AbbVie Inc; October 2021.
2. Ailani J, Lipton RB, Goadsby PJ, et al; ADVANCE Study Group. Atogepant for the preventive treatment of migraine. N Engl J Med. 2021;385(8):695-706. doi:10.1056/NEJMoa2035908[PubMed 34407343]
3. Boinpally R, Jakate A, Butler M, Borbridge L, Periclou A. Single-dose pharmacokinetics and safety of atogepant in adults with hepatic impairment: results from an open-label, phase 1 trial. Clin Pharmacol Drug Dev. 2021;10(7):726-733. doi:10.1002/cpdd.916[PubMed 33501783]
4. Ha H, Gonzalez A. Migraine headache prophylaxis. AFP. 2019;99(1):17-24.

MedOne P&T Committee approval: Date: 12-15-2022

Adopted: 9-28-21

Revised: 2-17-22
12-14-2022

Updates:

2-17-22
1. Removed concomitant use of acute CGRP restriction
2. Added needle phobia to fail first criteria

3-31-22
1. Updated AWP to current 3-31-22 price

12-14-22
1. Added pregabalin and nortriptyline to list of preferred generic preventative medications

Effective Date (most recent revisions): 2-1-2023

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

UM PROGRAM CRITERIA REVISED			
Ubrelvy (ubrogepant)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy
Ubrelvy	2. Added pregabalin and nortriptyline to list of preferred generic preventative medications		

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)
    - Nortriptyline (Pamelor)
    - 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)
    - Pregabalin (Lyrica)
    - 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:

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

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Revised: 9-3-21
12-7-21
2-2-22
2-17-22
6-8-22
12-14-2022

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
    - 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.
- 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

12-14-22
1. Added pregabalin and nortriptyline to list of preferred generic preventative medications

Effective Date (most recent revisions): 2-1-2023

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