COUPE HEALTH

PHARMACY UTILIZATION MANAGEMENT (UM) PROGRAM CRITERIA ACTIVITY

Provider Notification

Policies Effective: July 11, 2022 Notification Posted: May 25, 2022

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

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Ajovy (frenmanezumab)	1. Added step therapy with Aimovig and Emgality 2. Added no concomitant treatment with other CGRP criteria 3. Added Botox to step criteria 4. Added Patient is not concomitantly taking another CGRP antagonist or inhibitor for routine prophylaxis (Aimovig, Emgality, Vyepti). 5. 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 6. Removed concomitant use of acute CGRP restriction 7. 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)" 8. Added definition of chronic migraine of symptoms lasting longer than 3 months. 9. Updated AWP to current 3-31-22 price		

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)
    - 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
    - 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: 9-14-2018

Adopted:	9-14-2018
Revised:	9-3-2021 12-7-2021 2-17-2022 3-31-21

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

Effective Date (most recent revisions): 7-1-22

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

UM PROGRAM CRITERIA REVISED			
Aimovig (erenumab)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy
Aimovig (erenumab)	1. Added no concomitant treatment with other CGRP criteria 2. Added Botox to step criteria 3. Added Patient is not concomitantly taking another CGRP antagonist or inhibitor for routine prophylaxis (Ajovy, Emgality, Vyepti). 4. 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 5. Removed concomitant use of acute CGRP restriction 6. 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)" 7. Added definition of chronic migraine of symptoms lasting longer than 3 months. 8. Updated AWP to current 3-31-22 price		

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
  - 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: 5-17-2018

Adopted: 5-17-2018

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

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
2. 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)"
3. Added definition of chronic migraine of symptoms lasting longer than 3 months.
4. Updated AWP to current 3-31-22 price

Effective Date (most recent revisions): 7-1-22

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NEW UM PROGRAM CRITERIA			
Besremi (ropeginterferon alfa-2b-njft)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☐ Step Therapy

Prior Authorization Approval Criteria

Besremi (ropeginterferon alfa-2b-njft)

Generic name: ropeginterferon alfa-2b-njft
Brand name: Besremi
Medication class: Immunomodulator/Interferon
FDA-approved uses: Treatment of polycythemia vera in adults.

Usual dose range:

In patients not already on hydroxyurea	100 mcg initially SUBQ once every 2 weeks. Increase the dose by 50 mcg every 2 weeks (maximum: 500 mcg), until hematological parameters are stabilized (hematocrit <45%, platelets <400,000/mm^3, and leukocytes <10,000/mm^3).
In patients transitioning from hydroxyurea	50 mcg initially SUBQ once every 2 weeks (in combination with hydroxyurea). Increase the dose by 50 mcg every 2 weeks (maximum: 500 mcg), until hematological parameters are stabilized (hematocrit <45%, platelets <400,000/mm^3, and leukocytes <10,000/mm^3). Gradually taper the hydroxyurea off by reducing the total biweekly hydroxyurea dose by 20% to 40% every 2 weeks during weeks 3 to 12; discontinue hydroxyurea by week 13.

Duration of Authorization:

Initial:	3 months
Ongoing:	3 months

Criteria for use for polycythemia vera

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan
- Patient must be at least 18 years of age
- Must be prescribed by, or in consultation with a board-certified oncologist or hematologist.
- Patient must have laboratory confirmation of polycythemia vera (results from the approved test must be submitted for review).
- Dose does not exceed 2 syringes (500mcg/ml each) per 28 days.

Criteria continuation of therapy:

- Patient must be achieving clinical benefit from the treatment without unacceptable toxicity
- Disease progression on therapy has not occurred
- Patient has demonstrated a minimum medication possession ratio of at least 80% unless clinical rational is provided to justify holding treatment

Contraindications:

- Hypersensitivity to interferons, including interferon alfa-2b, or any component of the formulation.
- Existence of, or history of severe psychiatric disorders, particularly severe depression, suicidal ideation, or suicide attempt.
- Moderate (Child-Pugh class B) or severe (Child-Pugh class C) hepatic impairment.
- History or presence of active serious or untreated autoimmune disease.
- Immunosuppressed transplant recipients.

Not approved if:

- Disease progression has occurred while on therapy
- Patient has experienced an unacceptable toxicity while on treatment

Special considerations:

- Decreased peripheral blood cell counts, such as thrombocytopenia and leukopenia (which may increase bleeding or infection risk, respectively), and anemia have occurred with use of interferon alfa products, including ropeginterferon alfa-2b; ≥ grade 3 thrombocytopenia, leukopenia (including serious infection), and anemia have been reported in patients receiving ropeginterferon alfa-2b.
- Cardiovascular toxicity has occurred in patients receiving interferon alfa products, including ropeginterferon alfa-2b; toxicities may include cardiomyopathy, myocardial infarction (MI), atrial fibrillation, and coronary artery ischemia. Avoid use in patients with severe or unstable cardiovascular disease such as uncontrolled hypertension, heart failure (≥ NYHA class 2), serious cardiac arrhythmia, significant coronary artery stenosis, unstable angina, or recent stroke or MI.
- Ropeginterferon alfa-2b therapy may impair the ability to drive and use machinery; patients should not drive or operate heavy machinery until they know how ropeginterferon alfa-2b affects them. If dizziness, somnolence, or hallucinations occur, patients should avoid driving or using heavy machinery.
- Serious or fatal ulcerative or hemorrhagic/ischemic colitis (some cases occurring as early as 12 weeks after therapy initiation) has been reported in patients receiving interferon alfa products. Symptoms may include abdominal pain, bloody diarrhea, and fever; colitis may resolve within 1 to 3 weeks after treatment discontinuation.
- Dermatologic toxicity has been observed with interferon alfa products, including ropeginterferon alfa-2b. Toxicities may include skin rash, pruritus, alopecia, erythema, psoriasis, xeroderma, dermatitis acneiform, hyperkeratosis, and hyperhidrosis.

References:

1. Besremi (ropeginterferon alfa-2b) [prescribing information]. Burlington, MA: PharmaEssentia USA Corporation; November 2021.
2. Gisslinger H, Zagrijtschuk O, Buxhofer-Ausch V, et al. Ropeginterferon alfa-2b, a novel IFNα-2b, induces high response rates with low toxicity in patients with polycythemia vera. Blood. 2015;126(15):1762-1769. doi:10.1182/blood-2015-04-637280[PubMed 26261238]

MedOne Clinical Review Board approval: Date: 5/12/2022

Adopted:
Revised :

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

UM PROGRAM CRITERIA REVISED			
Brand Topical Acne Medications			
Program Type:	☒ Prior Authorization	☐ Quantity Limit	☒ Step Therapy
Brand Topical Acne Medications	1. Updated fail first criteria to include use of generic combinations products in addition to single product medications.		

Prior Authorization Approval Criteria

Brand Topical Acne Medications

**Class level criteria to be used in the absence of product specific criteria.*
Products listed are for example purposes only and are not meant to be all inclusive.
Any product specific criteria supersede criteria in class specific criteria.

Generic name	Azelaic Acid	Benzoyl Peroxide	Clindamycin Phosphate	Dapsone	Erythromycin	Minocycline
Trade name	Azelex	Benzac AC Benzepro Benziq Wash	Cleocin-T Clindacin ETZ Clindacin P Clindagel Evoclin	Aczone Gel	Ery Pads Erygel	Amzeeq
Approved age	12 years and older	18 years and older	12 years and older	9 years and older	18 years and older	9 years and older
Generic name	Sulfacetamide	Adapalene	Tretinoin	Tazarotene	Trifarotene	Salicylic Acid
Trade name	Klaron	Differin	Altreno* Atralin Avita Retin-A Retin-A Micro Tretin-X	Arazlo* Fabior Tazorac 0.1%	Aklief	Acnesic Gel Keralyt Gel
Approved age	12 years and older	12 years and older	12 years and older *Altreno – 10 years and older	12 years and older *Arazlo – 9 years and older	9 years and older	No minimum age noted for acne indication

Medication class: Topical dermatologic products
FDA-approved uses: Acne Vulgaris

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

Criteria for use for Acne Vulgaris

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
    - Over the counter trials and trials completed prior to starting on benefit will require trial dates and outcomes for each medication for consideration of trial.
- Grandfather criteria allowed
    - Please see policy and procedure “14 – Grandfather Status Authorization” for additional information

- Patient has failure, contraindication, or intolerance to TWO generic topical acne medications
    - Generic topical antibiotics (azelaic acid, benzoyl peroxide, clindamycin, dapsone, erythromycin, minocycline, sulfacetamide), including over the counter products
    - Generic topical salicylic acid, including over the counter products
    - Generic topical retinoids (adapalene, tretinoin, tazarotene, trifarotene), including over the counter products
    - Generic combination products
- The use of generic oral antibiotics (minocycline, doxycycline) for the treatment of acne are encouraged, but not required.

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. Summitted clinical documentation must be from an encounter after the start date of the current approval.
- Patient has filled at least one time in the last 180 days.

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- Clindamycin
    - Hypersensitivity to preparations containing clindamycin or lincomycin, history of regional enteritis or ulcerative colitis, or history of antibiotic-associated colitis.
- Erythromycin
    - Documentation of allergenic cross-reactivity for erythromycin is limited. However, because of similarities in chemical structure and/or pharmacologic actions, the possibility of cross-sensitivity cannot be ruled out with certainty.
- Sulfacetamide
    - Although the FDA-approved product labeling states this medication is contraindicated in patients with hypersensitivity to sulfonamide-containing drugs, the scientific basis of this cross-sensitivity has been challenged. See “Warnings/Precautions” for more detail.
- Adapalene
    - Documentation of allergenic cross-reactivity for retinoids is limited. However, because of similarities in chemical structure and/or pharmacologic actions, the possibility of cross-sensitivity cannot be ruled out with certainty.
- Tretinoin
    - Documentation of allergenic cross-reactivity for retinoids is limited. However, because of similarities in chemical structure and/or pharmacologic actions, the possibility of cross-sensitivity cannot be ruled out with certainty.
- Tazarotene
    - Pregnancy.
    - Documentation of allergenic cross-reactivity for retinoids is limited. However, because of similarities in chemical structure and/or pharmacologic actions, the possibility of cross-sensitivity cannot be ruled out with certainty.
- Trifarotene
    - Documentation of allergenic cross-reactivity for retinoids is limited. However, because of similarities in chemical structure and/or pharmacologic actions, the possibility of cross-sensitivity cannot be ruled out with certainty.
- Salicylic Acid

- Documentation of allergenic cross-reactivity for salicylates is limited. However, because of similarities in chemical structure and/or pharmacologic actions, the possibility of cross-sensitivity cannot be ruled out with certainty.

Not approved if:

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

Special Considerations:

- Azelic Acid
  - Skin irritation (eg, pruritus, burning, stinging) may occur, usually during the first few weeks of therapy. Discontinue use if severe skin irritation or sensitivity occurs.
  - A few cases of hypopigmentation after use have been reported; monitor for changes in skin color, especially in patients with dark complexions.
  - For external use only; not for oral, ophthalmic, or vaginal use; avoid contact with the eyes, mouth, and other mucous membranes. Use of occlusive dressings or wrappings should be avoided.
  - 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. Thrombocytopenia, ascites, pulmonary deterioration, and renal and hepatic failure have been reported in premature neonates after receiving parenteral products containing polysorbate 80.
- Benzoyl Peroxide
  - For external use only; avoid contact with eye, eyelids, lips, mouth, and mucous membranes. Inform patients to use skin protection (eg, sunscreen) and minimize prolonged exposure to sun or tanning beds.
  - Skin irritation (eg, burning, itching, peeling, redness, swelling) may occur; discontinue use if severe irritation develops.
  - May bleach hair, colored fabric, or carpet.
  - With benzoic acid derivatives (eg, cinnamon, certain topical anesthetics), cross-sensitization may occur.
  - Concomitant use of benzoyl peroxide with sulfone products (eg, dapsone, sulfacetamide) may cause temporary discoloration (yellow/orange) of facial hair and skin. Application of products at separate times during the day or washing off benzoyl peroxide prior to application of other products may avoid skin discoloration.
  - Some dosage forms may contain benzyl alcohol. Large amounts of benzyl alcohol (99 mg/kg/day or more) have been associated with a potentially fatal toxicity ("gasping syndrome") in neonates; the "gasping syndrome" consists of metabolic acidosis, respiratory distress, gasping respirations, CNS dysfunction (including convulsions, intracranial hemorrhage), hypotension, and cardiovascular collapse.
- Clindamycin
  - Use may result in fungal or bacterial superinfection, including Clostridioides difficile-associated diarrhea (CDAD); CDAD has been observed >2 months postantibiotic treatment. Discontinue drug if significant diarrhea, abdominal cramps, or passage of blood and mucus occurs.
  - Topical foam may cause irritation, especially when used with abrasive, desquamating, or peeling agents; avoid contact with eyes, mouth, lips, mucous membranes, or broken skin.
  - American Academy of Dermatology (AAD) acne guidelines recommend clindamycin (topical) be used in conjunction with other therapies (not as monotherapy) due to the risk of bacterial resistance. If given for mild acne, clindamycin (topical) should be used in combination with benzoyl peroxide. If given for moderate to severe acne, it should be used in combination with a topical retinoid or systemic antibiotic agent.

    - Some dosage forms may contain benzyl alcohol. Large amounts of benzyl alcohol (99 mg/kg/day or more) have been associated with a potentially fatal toxicity ("gasping syndrome") in neonates; the "gasping syndrome" consists of metabolic acidosis, respiratory distress, gasping respirations, CNS dysfunction (including convulsions, intracranial hemorrhage), hypotension, and cardiovascular collapse.
- Dapsone
    - Cases of methemoglobinemia, resulting in hospitalization, have been reported with twice-daily dapsone 5% gel. Patients with glucose-6-phosphate dehydrogenase deficiency or congenital or idiopathic methemoglobinemia are at increased risk; avoid use in patients with congenital or idiopathic methemoglobinemia. Dapsone may increase methemoglobin levels, especially in combination with methemoglobin-inducing agents. Signs and symptoms of methemoglobinemia (eg, slate-gray cyanosis in buccal mucous membranes, lips, and nail beds) may be delayed hours after exposure; discontinue dapsone treatment promptly and seek immediate medical attention in the event of cyanosis.
    - Changes suggestive of hemolysis have been observed in some patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency and using twice-daily dapsone 5% gel. Discontinue use of dapsone with signs/symptoms of hemolytic anemia. Do not use concomitantly with oral dapsone or other antimalarial agents due to increased risk of hemolytic reactions.
    - Has been reported with oral dapsone; similar events were not observed during clinical trials with topical dapsone.
    - Localized discoloration (yellow or orange) of the skin or facial hair may occur if benzoyl peroxide is used subsequent to dapsone gel; typically resolves in approximately 1 to 8 weeks. Skin reactions (eg, bullous and exfoliative dermatitis, erythema multiforme, erythema nodosum, morbilliform and scarlatiniform reactions, toxic epidermal necrolysis, urticaria) have been reported with oral dapsone; similar events were not observed during clinical trials with topical dapsone.
- Erythromycin
    - The American Academy of Dermatology acne guidelines recommend erythromycin (topical) be used in conjunction with other therapies (not as monotherapy) due to the risk of bacterial resistance. If given for mild acne, erythromycin (topical) should be used in combination with benzoyl peroxide. If given for moderate to severe acne, it should be used in combination with a topical retinoid or systemic antibiotic agent.
    - For topical use only; not for ophthalmic use. Avoid contact with eyes, nose, mouth, mucous membranes, or broken skin. Lack of improvement or worsening of acne may indicate microbial resistance. Alternative therapy may be required for severe acne (eg, nodular). Consider alternate therapy in patients with poor tolerance to macrolides or clindamycin.
    - Use with caution, especially with peeling, desquamating, or abrasive agents; irritation may be cumulative. Discontinue use if irritation or dermatitis occurs.
    - May be flammable. Keep away from heat and flame.
- Minocycline
    - Foam contains flammable propellants. Avoid fire, flame, and smoking during and immediately following application.
    - The American Academy of Dermatology acne guidelines generally recommend topical antibiotics be used in conjunction with other therapies (not as monotherapy) due to the risk of bacterial resistance.
    - Serious liver injury, including irreversible drug-induced hepatitis and fulminant hepatic failure (sometimes fatal) have been reported with oral minocycline.
    - Lupus-like, hepatitis, and vasculitis autoimmune syndromes (including serum sickness [eg, fever, arthralgia, malaise]) have been reported with oral minocycline; immediately discontinue if symptoms occur.
    - Intracranial hypertension (eg, headache, blurred vision, diplopia, vision loss, papilledema) has been associated with use of tetracyclines. Women of childbearing age who are overweight or have a

history of intracranial hypertension are at greater risk. Concomitant use of isotretinoin (known to cause intracranial hypertension) and minocycline should be avoided. Intracranial hypertension typically resolves after discontinuation of treatment; however, permanent visual loss is possible. If visual symptoms develop during treatment, prompt ophthalmologic evaluation is warranted. Intracranial pressure can remain elevated for weeks after drug discontinuation; monitor patients until they stabilize.
    - May be associated with increases in BUN secondary to antianabolic effects of tetracyclines.
- Sulfacetamide
    - Fatalities associated with severe reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis, and drug fever, have occurred with sulfonamides (regardless of route). In addition, contact dermatitis, reddening, and scaling of the skin may occur.
    - Fatalities associated with severe reactions, including agranulocytosis, acute hemolytic anemia, aplastic anemia, purpura hemorrhagica, and other blood dyscrasias, have occurred with sulfonamides (regardless of route).
    - Fatalities associated with severe reactions, including fulminant hepatic necrosis and jaundice, have occurred with sulfonamides (regardless of route).
    - Fatalities associated with severe reactions, including drug-induced systemic lupus erythematosus, have occurred with sulfonamides (regardless of route).
    - Application to infected area containing nonsusceptible organisms may cause proliferation of the organism.
    - For external use only; not for ophthalmic use; avoid contact with eyes and mucous membranes. Discontinue use if irritation, rash, or signs of hypersensitivity occur. Monitor closely for local irritation and/or sensitization during long-term therapy.
    - The FDA-approved product labeling for many medications containing a sulfonamide chemical group includes a broad contraindication in patients with a prior allergic reaction to sulfonamides. There is a potential for cross-reactivity between members of a specific class (eg, two antibiotic sulfonamides). However, concerns for cross-reactivity have previously extended to all compounds containing the sulfonamide structure (SO2NH2). An expanded understanding of allergic mechanisms indicates cross-reactivity between antibiotic sulfonamides and nonantibiotic sulfonamides may not occur or, at the very least, this potential is extremely low.Ref In particular, mechanisms of cross-reaction due to antibody production (anaphylaxis) are unlikely to occur with nonantibiotic sulfonamides. T-cell-mediated (type IV) reactions (eg, maculopapular rash) are less well understood and it is not possible to completely exclude this potential based on current insights. In cases where prior reactions were severe (Stevens-Johnson syndrome/toxic epidermal necrolysis), some health care providers choose to avoid exposure to these classes.
    - Systemic absorption is increased with application to large, infected, abraded, denuded, or burned skin.
    - Some products contain sodium metabisulfite, which may cause allergic reactions in certain individuals (eg, asthmatic patients).
- Adapalene
    - Certain cutaneous signs and symptoms such as erythema, dryness, scaling, stinging/burning, or pruritus may occur during treatment; these are most likely to occur during the first 2 to 4 weeks and will usually lessen with continued use. Treatment can increase skin sensitivity to weather extremes of wind or cold. Concomitant topical medications (eg, medicated or abrasive soaps and cleansers, or cosmetics with a strong drying effect, products with high concentrations of alcohol, astringents, spices or limes) should be avoided due to increased skin irritation. Depending on the severity of irritation, use moisturizer, reduce the frequency of application, or discontinue use.
    - For external use only; avoid contact with abraded, broken, eczematous, or sunburned skin, mucous membranes, eyes, lips, and angles of the nose. Wax depilation is not recommended.
- Tretinoin

    - Treatment can increase skin sensitivity to weather extremes of wind or cold. Excessive dryness, redness, and swollen or blistered skin may occur. Also, concomitant topical medications (eg, medicated or abrasive soaps, cleansers, or cosmetics with a strong drying effect) should be used with caution due to increased skin irritation. Depending on the severity of irritation, use a moisturizer, reduce the amount or frequency, or discontinue use until irritation disappears.
    - Use with caution in patients with eczema; may cause severe irritation.
    - For external use only; avoid contact with abraded skin, sunburned skin, mucous membranes, eyes, mouth, angles of the nose. When used for palliation of fine wrinkles, mottled hyperpigmentation, or facial skin roughness, should be used as part of a comprehensive skin care and sun avoidance program.
- Tazarotene
    - For external use only; avoid contact with eyes, eyelids, and mouth. Not for use on eczematous, abraded, broken, or sunburned skin; not for treatment of lentigo maligna. Avoid application over extensive areas. The efficacy of tazarotene gel in the treatment of acne previously treated with other retinoids or resistant to oral antibiotics has not been established.
    - Local tolerability reactions (including blistering or skin desquamation) or local hypersensitivity reactions (including urticaria) may occur. Application site pain, excessive burning, drying, pruritus, peeling, and skin redness may occur, especially during the early weeks of treatment. Treatment can increase skin sensitivity to weather extremes of wind or cold. Concomitant topical medications (eg, medicated or abrasive soaps, cleansers, or cosmetics with a strong drying effect) should be avoided due to increased skin irritation. Depending on the severity of the reaction, instruct patients to use a moisturizer, reduce the frequency of use, or discontinue use.
    - Some dosage forms may contain benzyl alcohol. Large amounts of benzyl alcohol (99 mg/kg/day or more) have been associated with a potentially fatal toxicity ("gasping syndrome") in neonates; the "gasping syndrome" consists of metabolic acidosis, respiratory distress, gasping respirations, CNS dysfunction (including convulsions, intracranial hemorrhage), hypotension, and cardiovascular collapse. Some data suggest that benzoate displaces bilirubin from protein-binding sites.
- Trifarotene
    - Erythema, scaling, dryness, and stinging or burning of skin may occur. Onset and worsening is most common within the first 4 weeks of treatment and often decreases with continued use. Concomitant topical medications (eg, medicated or abrasive soaps and cleansers, cosmetics with a strong drying effect, products with high concentrations of alcohol) should be avoided due to increased skin irritation. Use of a moisturizer, reduced frequency of application, or temporary discontinuation may be considered based on the reaction severity; permanent discontinuation may be considered for severe, persistent reactions.
    - Use is associated with increased susceptibility/sensitivity to UV light; avoid or minimize excessive exposure to sunlamps or sunlight. Daily sunscreen (SPF ≥15) use and other protective measures (eg, clothing over treated areas) are recommended.
    - Use with caution in patients with eczema; may cause severe irritation.
    - For external use only; avoid contact with abraded skin, sunburned skin, mucous membranes, eyes, mouth, and angles of the nose. Hair removal via waxing should be avoided on treated areas.
- Salicylic Acid
    - Do not combine use of topical salicylic acid with use of other salicylates or drugs that can increase salicylate serum concentrations; systemic absorption following topical use may occur and lead to toxicity.
    - Apply to affected areas only. Do not apply to broken skin or large areas of body. Dryness or irritation may be increased if other topical acne products are used at the same time. If irritation occurs, use only one topical acne product at a time. New users may test for sensitivity by applying the product sparingly to 1 to 2 affected areas for the first 3 days; if no discomfort occurs, may continue with directions on product labeling. May increase skin sensitivity to sunburn; use sunscreen and limit sun exposure during use and for 1 week afterward.

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MedOne P&T Committee approval: Date: 4-28-22

Initial adoption: 4-28-22
Revised: 4-29-22
4-29-22
1. Updated fail first criteria to include use of generic combinations products in addition to single product medications.

Effective Date (most recent revisions): 7/1/2022

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

UM PROGRAM CRITERIA REVISED			
Brand Topical Combination Acne Medications			
Program Type:	☒ Prior Authorization	☐ Quantity Limit	☒ Step Therapy
Brand Topical Combination Acne Medications	1. Updated fail first criteria to include use of generic combinations products in addition to single product medications and removed requirement to use of active ingredients in brand product concurrently prior to authorization of brand product.		

Prior Authorization Approval Criteria

Brand Topical Combination Acne Medications

**Class level criteria to be used in the absence of product specific criteria.*
Products listed are for example purposes only and are not meant to be all inclusive.
Any product specific criteria supersede criteria in class specific criteria.

Generic name	Benzoyl Peroxide - Hydrocortisone	Benzoyl Peroxide – adapalene	Benzoyl Peroxide – Clindamycin	Benzoyl Peroxide – Erythromycin
Trade name	Vanoxide HC (5%-0.5%)	Epiduo (2.5%-0.1%)	Acanya (2.5%-1.2%) Onexton (3.75%-1.2%) BenzaClin (5%-1%) Duac (5%-1%) Duac (5%-1.2%)	Benzamycin (5%-3%) Benzamycin Pak (5%-3%)
Approved Age	12 years and older	9 years and older	12 years and older	12 years and older
Generic name	Benzoyl Peroxide – Sulfur	Benzoyl Peroxide – Tretinoin	Benzoyl Peroxide – Salicyclic Acid	Sulfur and Sulfacetamide
Trade name	NuOx (6%-3%)	Veltin (1.2%-0.025%) Ziana (1.2%-0.025%)	Inova 4/1 Acne Control Therapy Pads (4%-1%) Inova 8/2 Acne Control Therapy Pads (8%-2%)	Avar-e LS (2%-10%) Plexion (4.8%-9.8%) Avar-e Green (5%-10%) Plexion SCT (5%-10%) BP 10-1 (1%-10%) Sulfamez Wash (1%-10%) Clenia (5%-10%) Avar LS (2%-10%) Sumaxin CP (4%-10%) Sumadan (4.5%-9%) Sumaxin Wash (4%-9%) Rosanil Cleanser (5%-10%)
Approved Age	12 years and older	12 years and older	12 years and older	12 years and older

Medication class: Topical dermatologic products
FDA-approved uses: Acne Vulgaris

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

Criteria for use for Acne Vulgaris

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
    - Over the counter trials and trials completed prior to starting on benefit will require trial dates and outcomes for each medication for consideration of trial.
- Grandfather criteria allowed
    - Please see policy and procedure "14 – Grandfather Status Authorization" for additional information
- Patient has failure, contraindication, or intolerance to TWO generic topical acne medications
    - Generic topical antibiotics (azelaic acid, benzoyl peroxide, clindamycin, dapsone, erythromycin, minocycline, sulfacetamide), including over the counter products
    - Generic topical salicylic acid, including over the counter products
    - Generic topical retinoids (adapalene, tretinoin, tazarotene, trifarotene), including over the counter products
    - Generic combination products
- The use of generic oral antibiotics (minocycline, doxycycline) for the treatment of acne are encouraged, but not required.

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. Summitted clinical documentation must be from an encounter after the start date of the current approval.
- Patient has filled at least one time within the 180 days.

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- Benzoyl peroxide/clindamycin
    - Hypersensitivity to lincomycin; history of regional enteritis, ulcerative colitis, or antibiotic-associated colitis (including pseudomembranous colitis).
- Benzoyl peroxide/hydrocortisone
    - Viral diseases of the skin (eg, varicella).
- Sulfur and Sulfacetamide
    - Hypersensitivity to sulfur, sulfonamides, or any component of the formulation; renal disease.
    - Although the FDA-approved product labeling states this medication is contraindicated in patients with hypersensitivity to sulfonamide-containing drugs, the scientific basis of this cross-sensitivity has been challenged. See “Warnings/Precautions” for more detail.

Not approved if:

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

Special Considerations:

- Benzoyl Peroxide Combination Products
    - Systemic absorption may occur after topical use of antibiotics. Clostridioides difficile–associated diarrhea (CDAD) and pseudomembranous colitis have been reported and has been observed more than 2 months postantibiotic treatment. Use of parenteral and systemic antibiotics has resulted in severe colitis (including fatalities). Discontinue drug if significant diarrhea, abdominal cramps, or passage of blood and mucus occurs.
    - Benzoyl peroxide may bleach hair, colored fabrics, or carpeting.
    - For external use only; not for vaginal or ophthalmic use. Avoid contact with mucous membranes.
    - Certain cutaneous signs and symptoms (eg, erythema, dryness, scaling, burning/stinging) may occur with adapalene/benzoyl peroxide; these are most likely to occur during the first 4 weeks and usually lessen with continued use. Irritant and allergic contact dermatitis may occur. Use concomitant topical acne therapy with caution; cumulative irritancy may occur, especially with the use of peeling, desquamating, or abrasive agents. Use of moisturizer, decreased use, or discontinuation may be recommended.
    - Concomitant use of benzoyl peroxide with sulfone products (eg, dapsone, sulfacetamide) may cause temporary discoloration (yellow/orange) of facial hair and skin. Application of products at separate times during the day or washing off benzoyl peroxide prior to application of other products may avoid skin discoloration.
- Adapalene/Benzoyl peroxide
    - For external use only; avoid contact with abraded skin, mucous membranes, and eyes. Do not apply to cuts, abrasions, eczematous or sunburned skin. Avoid use of waxing as a depilatory method on treated skin. Avoid concomitant use of other potentially irritating topical products (medicated or

abrasive soaps and cleansers, soaps and cosmetics that have strong skin-drying effect and products with high concentrations of alcohol, astringents, spices, or limes).

- Sulfur and Sulfacetamide
    - Fatalities associated with severe reactions, including drug-induced systemic lupus erythematosus, have occurred with sulfonamides (regardless of administration route).
    - Fatalities associated with severe reactions, including agranulocytosis, acute hemolytic anemia, aplastic anemia, purpura hemorrhagica, and other blood dyscrasias, have occurred with sulfonamides (regardless of route).
    - Fatalities associated with severe reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis, and drug fever, have occurred with sulfonamides (regardless of route). In addition, contact dermatitis, reddening, and scaling of the skin may occur.
    - Fatalities associated with severe reactions, including fulminant hepatic necrosis and jaundice, have occurred with sulfonamides (regardless of route).
    - Traditionally, concerns for cross-reactivity have extended to all compounds containing the sulfonamide structure (SO2NH2). An expanded understanding of allergic mechanisms indicates cross-reactivity between antibiotic sulfonamides and nonantibiotic sulfonamides may not occur, or at the very least this potential is extremely low. In particular, mechanisms of cross-reaction due to antibody production (anaphylaxis) are unlikely to occur with nonantibiotic sulfonamides and antibiotic sulfonamides. A nonantibiotic sulfonamide compound which contains the arylamine structure and therefore may cross-react with antibiotic sulfonamides is sulfasalazine.
    - Systemic absorption is increased with application to large, infected, abraded, denuded, or burned skin.
    - Some dosage forms may contain benzyl alcohol; large amounts of benzyl alcohol (99 mg/kg/day or more) have been associated with a potentially fatal toxicity ("gasping syndrome") in neonates; the "gasping syndrome" consists of metabolic acidosis, respiratory distress, gasping respirations, CNS dysfunction (including convulsions, intracranial hemorrhage), hypotension, and cardiovascular collapse. Some data suggest that benzoate displaces bilirubin from protein binding sites. Avoid or use dosage forms containing benzyl alcohol with caution in neonates.

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MedOne P&T Committee approval: **Date:** 4-28-22

Initial adoption: 4-28-22
Revised: 4-29-22

4-29-22
1. Updated fail first criteria to include use of generic combinations products in addition to single product medications and removed requirement to use of active ingredients in brand product concurrently prior to authorization of brand product.

Effective Date (most recent revisions): 7-1-22

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

UM PROGRAM CRITERIA REVISED

Emgality (galcanezumab)

Program Type:	☒ Prior Authorization ☒ Quantity Limit ☒ Step Therapy
Emgality (galcanezumab)	1. Added no concomitant treatment with other CGRP criteria 2. Added Botox to step criteria 3. Added fail first criteria to cluster headache- verapamil 4. Added Patient is not concomitantly taking another CGRP antagonist or inhibitor for routine prophylaxis (Aimovig, Ajovy, Vyepti). 5. 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 6. Removed concomitant use of acute CGRP restriction 7. Updated "Patient is not concomitantly taking with another CGRP antagonist or inhibitor (Aimovig, Ajovy, Vyepti)" to ""Patient is not concomitantly taking with another CGRP antagonist or inhibitor (Aimovig, Ajovy, Qulipta, Vyepti)" 8. Added definition of chronic migraine of symptoms lasting longer than 3 months. 9. Updated AWP to current 3-31-22 price

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)
    - 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
    - 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.

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Adopted: 9-27-2018
Revised: 9-3-21
12-7-21
2-17-22
3-31-22

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
3. 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

Effective Date (most recent revisions): 7-1-22

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NEW UM PROGRAM CRITERIA			
Exkivity (mobocertinib)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☐ Step Therapy

Prior Authorization Approval Criteria

Exkivity (mobocertinib)

Generic name: mobocertinib
Brand name: Exkivity
Medication class: Epidermal Growth Factor Receptor (EGFR) Inhibitor / Tyrosine Kinase Inhibitor (TKI)
FDA-approved uses: To treat locally advanced or metastatic non-small cell lung cancer with epidermal growth factor receptor exon 20 insertion mutations

Usual dose range: 160 mg once daily until disease progression or unacceptable toxicity

Duration of Authorization:

Initial:	3 months
Ongoing:	3 months

Criteria for use for locally advanced or metastatic non-small cell lung cancer with epidermal growth factor receptor exon 20 insertion mutations

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan
- Patient must be at least 18 years of age
- Patient must have laboratory confirmation of non-small cell lung cancer with epidermal growth factor receptor exon 20 insertion mutations (results from the approved test must be submitted for review)
- Patient must have tried and failed, or be intolerant to at least one platinum-based chemotherapy regimen
- Dose does not exceed 160mg per day (4 capsules)

Criteria continuation of therapy:

- Patient must be achieving clinical benefit from the treatment without unacceptable toxicity
- Disease progression on therapy has not occurred
- Patient has demonstrated a minimum medication possession ratio of at least 80% unless clinical rational is provided to justify holding treatment

Contraindications:

- History of hypersensitivity to any of the product ingredients

Not approved if:

- Disease progression has occurred while on therapy

- Patient has experienced an unacceptable toxicity while on treatment

Special considerations:

- QT prolongation and torsades de pointes have been reported with increased risk in patients with congenital long QT syndrome, heart disease, or electrolyte abnormalities. Monitoring is recommended. Dosage adjustment, therapy interruption or discontinuation may be necessary
- Cardiac toxicity, including decreased ejection fraction, cardiomyopathy, and congestive heart failure, including fatalities, has been reported. Monitoring is recommended. Dosage adjustment, therapy interruption or discontinuation may be necessary
- Diarrhea, including severe cases, has been reported. Monitoring is recommended. Dosage adjustment, therapy interruption or discontinuation may be necessary
- Interstitial lung disease/pneumonitis, including fatalities, has been reported. Monitoring is recommended and interruption of therapy or permanent discontinuation may be required
- May cause fetal harm; advise females of reproductive potential to use an effective nonhormonal method of contraception during therapy and for at least 1 month after discontinuation
- Advise males with female partners of reproductive potential to use effective contraception during therapy and for at least 1 week after discontinuation

References:

1. Product Information: EXKIVITY(TM) oral capsules, mobocertinib oral capsules. Takeda Pharmaceuticals America Inc (per FDA), Lexington, MA, 2021.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 6.2021 – September 30, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www,nccn.org. Accessed on October 1, 2021.

MedOne Clinical Review Board approval: Date: 5/12/2022

Adopted:
Revised :

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NEW UM PROGRAM CRITERIA			
Livmarli - maralixibat			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy

Prior Authorization Approval Criteria

Livmarli - maralixibat

Generic name: maralixibat
Brand name: Livmarli
Medication class: Ileal Bile Acid Transporter Inhibitor
FDA-approved uses: To treat cholestatic pruritus associated with Alagille syndrome
Indication #2

Usual dose range:

Initial:	0.19 mg/kg/dose (maximum: 14.25 mg/dose) once daily for 7 days
Maintenance:	Increase to target dose of 0.38 mg/kg/dose (maximum: 28.5 mg/dose) once daily.
Maximum:	28.5 mg/day

Duration of Authorization:

Initial:	3 months
Ongoing:	12 months

Criteria for use for cholestatic pruritus associated with Alagille syndrome

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan
- Patient must have a diagnosis of Alagille syndrome confirmed by the presence of the JAG1 or Notch2 gene mutation (approved laboratory test result must be submitted for review)
- Patient must be at least 1 year of age
- Patient must have moderate to severe pruritis
- Patient must have tried and failed 2 preferred formulary alternatives (rifampin, cholestyramine, colesevelam, ursodiol)
- Must be prescribed by, or in consultation with, a board certified hepatologist
- Patient must have at least one of the following:
    - Total serum bile acid level > 3x ULN
    - Conjugated bilirubin level > 1mg/dL
    - Fat soluble vitamin deficiency not attributable to another indication
    - Gamma-glutamyl transferase level > 3x ULN

Criteria continuation of therapy:

- Patient must be achieving clinical benefit from the treatment without unacceptable toxicity
- Patient has demonstrated a minimum medication possession ratio of at least 80% unless clinical rational is provided to justify holding treatment
- Patient's laboratory metrics demonstrate improvement from baseline (reduced serium bile acids)

Contraindications:

- History of hypersensitivity to any of the product ingredients

Not approved if:

- Patient has cirrhosis, portal hypertension, history of hepatic decompensation

Special considerations:

- Fat-soluble vitamin (FSV) deficiency has been reported; obtain FSV levels at baseline and monitoring recommended. Supplementation or discontinuation may be necessary
- Diarrhea, abdominal pain, and vomiting have been reported; dosage adjustment, interruption, or discontinuation may be necessary

- Liver test abnormalities (eg, elevations or worsening of liver tests) have been reported; monitoring recommended and dose reduction, therapy interruption, or discontinuation may be necessary

References:

1. Livmarli [package insert]. Foster City, CA: Mirum Pharmaceuticals, Inc.; September 2021.
2. Alagille syndrome. National Organization for Rare Disorders. Updated 2020. Available at: https://rarediseases.org/rare-diseases/alagille-syndrome/.
3. Treatment for Alagille syndrome. National Institute of Diabetes and Digestive and Kidney Diseases. US Department of Health and Human Services. Updated January 2019.
4.

MedOne Clinical Review Board approval: Date: 5/12/2022

Adopted:
Revised :

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

Prior Authorization Approval Criteria

Livtencity (maribavir)

Generic name: maribavir
Brand name: Livtencity
Medication class: Antiviral Agent; Benzimidazole Riboside
FDA-approved uses: Post-transplant cytomegalovirus (CMV) infection/disease that does not respond (with or without genetic mutations that cause resistance) to available antiviral treatment for CMV

Usual dose range:

Post-transplant cytomegalovirus (CMV) infection/disease that does not respond (with or without genetic mutations that cause resistance) to available antiviral treatment for CMV	400 mg twice daily

Duration of Authorization:
Initial: 56 days

Ongoing: Not applicable, acute treatment only

Criteria for use for post-transplant cytomegalovirus (CMV) infection/disease that does not respond (with or without genetic mutations that cause resistance) to available antiviral treatment for CMV

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan
- Patient is at least 12 years of age and at least 35kg
- Patient must have a recent history of solid organ or hematopoietic transplant
- Patient has active cytomegalovirus infection
- Patient has tried and failed at least one, or has contraindications to all, preferred treatments for active cytomegalovirus infection
    - cidofovir
    - foscarnet
    - ganciclovir
    - valganciclovir
- The medication is prescribed by a board-certified hematologist, infections disease specialist, oncologist, or transplant physician

Criteria continuation of therapy:

- Authorization is limited to one 8-week acute treatment course. Extended treatment is not recommended. Reauthorization is not allowed.

Contraindications:

- History of hypersensitivity to any of the product ingredients

Not approved if:

- Use is for the prevention of cytomegalovirus (CMV) infection/disease
- Patients are concurrently taking ganciclovir or valganciclovir

Special considerations:

- Coadministration with ganciclovir or valganciclovir is not recommended
- Known or potentially significant drug interactions leading to adverse events, loss of virologic response and possible development of viral resistance may occur with the concomitant use of other agents; review concomitant medications prior to and during treatment
- Concomitant use with strong inducers of CYP3A4 (except selected anticonvulsants) is not recommended
- Virologic failure due to resistance may occur during and after treatment; monitoring recommended

References:

1. Livtencity™ tablets [prescribing information]. Lexington, MA: Takeda; November 2021
2. Maertens J, Cordonnier C, Jaksch P, et al. Maribavir for preemptive treatment of cytomegalovirus reactivation. N Engl J Med. 2019;381:1136-1147
3. Papanicolaou GA, Silveira FP, Langston AA, et al. Maribavir for refractory or resistant cytomegalovirus infections in hematopoietic-cell or solid-organ transplant recipients: a

randomized, dose-ranging, double-blind, phase 2 study. Clin Infect Dis. 2019;68(8):1255-1264. doi:10.1093/cid/ciy706

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NEW UM PROGRAM CRITERIA			
darifenacin tablets (generic)			
Program Type:	☐ Prior Authorization	☒ Quantity Limit	☐ Step Therapy

Prior Authorization Approval Criteria

darifenacin tablets (generic)

Generic name: darifenacin tablets
Brand name: Enablex (brand product has been discontinued)
Medispan GPI: 541000102075** Y
Medication class: Urinary Anticholinergic
FDA-approved uses: **Overactive Bladder**

Usual dose range:

Overactive Bladder	Initial: 7.5mg once daily	Maintenance: May increase to 15 mg once daily after a minimum of 2 weeks if response not adequate.

Duration of Authorization:
Ongoing: Will be ongoing for generic products.

Criteria for use for Overactive Bladder

- 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.
- Patient is clinically diagnosed with overactive bladder with symptoms of urinary frequency, urgency, or urge incontinence.

Criteria continuation of therapy

- Not applicable, authorization will be ongoing for generic products.

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- Patients with or at risk of uncontrolled narrow-angle glaucoma, urinary retention, gastric retention.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- Patients under the age of 18, safety and effectiveness have not been established.
- Use is not recommended in patients with severe hepatic impairment (Child-Pugh class C).

Special Considerations:

- In patients with impaired hepatic function (Child-Pugh class B) a maximum of 7.5mg/day is recommended.
- Angioedema involving the face, lips, tongue, and/or larynx have been reported; some cases have occurred after the first dose. May be life-threatening. Immediately discontinue and institute supportive care if tongue, hypopharynx, or larynx is involved.
- CNS effects have been reported (eg, headache, confusion, hallucinations, somnolence); monitor for CNS effects, particularly at treatment initiation or dose increase; reduce dose or discontinue if necessary. May cause drowsiness and/or blurred vision, which may impair physical or mental abilities; patients must be cautioned about performing tasks which require mental alertness (eg, operating machinery or driving).
- May occur in the presence of increased environmental temperature; use caution in hot weather and/or exercise.

References:

1. Enablex (darifenacin) [prescribing information]. Madison, NJ: Allergan USA Inc; received July 2021.

MedOne P&T Committee approval: Date: 5-19-2022

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NEW UM PROGRAM CRITERIA			
oxybutynin IR/ER tablets (generic)			
Program Type:	☐ Prior Authorization	☒ Quantity Limit	☐ Step Therapy

Prior Authorization Approval Criteria

oxybutynin IR/ER tablets (generic)

Generic name:	oxybutynin IR/ER tablets	
Brand name:	Ditropan XL	
Medispan GPI:	IR - 541000452003** ER - 541000452075**	Y
Medication class:	Urinary Anticholinergic	
FDA-approved uses:	**Overactive Bladder** **Neurogenic Overactive Bladder (pediatric)**	
Usual dose range:		
Overactive Bladder – IR tablets	Initial: 5mg 2-3 times daily	Maintenance: 5mg 4 times daily

Overactive Bladder – ER tablets	Initial: 5-10mg once daily	Maintenance: 30mg once daily
Neurogenic Overactive Bladder (pediatric) – IR	Initial 5mg twice daily *in children 5 years and older	Maintenance: 5mg 4 times daily
Neurogenic Overactive Bladder (pediatric) – ER	Initial 5mg once daily *in children 6 years and older	Maintenance: 20mg once daily

Duration of Authorization:

Ongoing: Will be ongoing for generic products.

Criteria for use for Overactive Bladder

- 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.
- Patient is clinically diagnosed with overactive bladder (eg, urge urinary incontinence, urgency, frequency, urinary leakage, dysuria)

Criteria for use for Neurogenic Overactive Bladder (pediatric)

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be 5 years of age or older for immediate release tablets, 6 years of age or older for extended release tablets.
- Patient is clinically diagnosed with overactive bladder due to a neurological condition (eg, spina bifida).

Criteria continuation of therapy

- Not applicable, authorization will be ongoing for generic products.

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- Patients with or at risk of uncontrolled narrow-angle glaucoma, urinary retention, gastric retention.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- In patients under the age of 5.

Special Considerations:

- The ER formulation consists of drug within a nondeformable matrix; following drug release/absorption, the matrix/shell is expelled in the stool. The use of nondeformable products in patients with known stricture/narrowing of the GI tract has been associated with symptoms of obstruction (rare).
- May increase the risk of this illness with intense exertion in the heat.
- Use with caution in patients with dementia treated with cholinesterase inhibitors; may aggravate symptoms of disease.

References:

1. Ditropan XL (oxybutynin chloride) extended-release tablets [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals Inc; received April 2021.

MedOne P&T Committee approval: Date: 5-19-2022

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NEW UM PROGRAM CRITERIA			
solifenacin (generic)			
Program Type:	☐ Prior Authorization	☒ Quantity Limit	☐ Step Therapy

Prior Authorization Approval Criteria

solifenacin (generic)

Generic name:	solifenacin tablets	
Brand name:	Vesicare	
Medispan GPI:	541000552003**	Y
Medication class:	Urinary Anticholinergic	
FDA-approved uses:	**Overactive Bladder**	
Usual dose range:		
Overactive Bladder	Initial: 5mg once daily	Maintenance: If the 5 mg dose is well tolerated, may increase to 10 mg once daily.

Duration of Authorization:

Ongoing: Will be ongoing for generic products.

Criteria for use for Overactive Bladder

- 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.
- Patient is clinically diagnosed with overactive bladder with symptoms of urinary frequency, urgency, or urge incontinence in adults.

Criteria continuation of therapy

- Not applicable, authorization will be ongoing for generic products

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- Patients with or at risk of uncontrolled narrow-angle glaucoma, urinary retention, gastric retention.

Not approved if:

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

- Patients under the age of 18, safety and effectiveness have not been established.

Special Considerations:

- In patients with impaired renal function (CrCl <30mL/minute) – maximum of 5mg per day for adults.
- In patients with impaired hepatic function (Child-Pugh class B) – maximum of 5mg per day for adults.
- Angioedema involving the face, lips, tongue, and/or larynx have been reported; some cases have occurred after the first dose. May be life-threatening. Immediately discontinue and institute supportive care if tongue, hypopharynx, or larynx is involved.
- CNS effects have been reported (eg, headache, confusion, hallucinations, somnolence); monitor for CNS effects, particularly at treatment initiation or dose increase; reduce dose or discontinue, if necessary. May cause drowsiness and/or blurred vision, which may impair physical or mental abilities; patients must be cautioned about performing tasks that require mental alertness (eg, operating machinery, driving).
- May occur in the presence of increased environmental temperature; use caution in hot weather and/or exercise.

References:

1. VESIcare (solifenacin succinate) [prescribing information]. Northbrook, IL: Astellas Pharma US; May 2020.

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NEW UM PROGRAM CRITERIA			
tolterodine IR/ER (generic)			
Program Type:	☐ Prior Authorization	☒ Quantity Limit	☐ Step Therapy

Prior Authorization Approval Criteria

tolterodine IR/ER (generic)

Generic name:	tolterodine IR/ER	
Brand name:	Detrol / Detrol LA	
Medispan GPI:	IR 541000602003** ER 541000602070**	Y
Medication class:	Urinary Anticholinergic	
FDA-approved uses:	**Overactive Bladder**	
Usual dose range:		
Overactive Bladder – IR tablets	Initial: 2mg twice daily	Maintenance: Decrease the dosage to 1 mg twice daily based on individual response and tolerability.

Overactive Bladder – ER tablets	Initial: 4mg once daily	Maintenance: Decrease the dosage to 2 mg once daily based on individual response and tolerability.

Duration of Authorization:

Ongoing: Will be ongoing for generic products.

Criteria for use for Overactive Bladder

- 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.
- Patient is clinically diagnosed with overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency.

Criteria continuation of therapy

- Not applicable, will be ongoing for generic products.

Contraindications:

- History of hypersensitivity to any of the product ingredients or fesoterodine.
- Patients with or at risk of uncontrolled narrow-angle glaucoma, urinary retention, gastric retention.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- Patients under the age of 18, safety and effectiveness have not been established.
- Use of ER tablets is not recommended in patients with creatinine clearance less than 10 mL/min
- Use is not recommended in patients with severe hepatic impairment (Child-Pugh class C).

Special Considerations:

- In patients with impaired renal function (CrCl 10-30mL/min) 2mg per day for ER tablets, and in patients with significantly reduced renal function 1mg twice daily for IR tablets.
- In patients with impaired hepatic function (Child-Pugh class A or B) 2mg per day for ER tablets, and in patients with significantly reduced hepatic function 1mg twice daily for IR tablets.
- Cases of angioedema have been reported; some cases have occurred after a single dose. Discontinue immediately if angioedema and associated difficulty breathing, airway obstruction, or hypotension develop.
- May cause drowsiness, dizziness, and/or blurred vision, which may impair physical or mental abilities; patients must be cautioned about performing tasks which require mental alertness (eg, operating machinery or driving). Dose reduction or discontinuation should be considered if CNS effects occur.
- Has been associated with QTc prolongation at high (supratherapeutic) doses. The manufacturer recommends caution in patients with congenital prolonged QT or in patients receiving concurrent therapy with QTc-prolonging drugs (class Ia or III antiarrhythmics). However, the extent of QTc prolongation even at supratherapeutic dosages was less than 15 msec. Individuals who are CYP2D6 poor metabolizers or in the presence of inhibitors of CYP2D6 and CYP3A4 may be more likely to exhibit prolongation.

References:

1. Detrol LA (tolterodine) [prescribing information]. New York, NY: Pfizer; July 2018.
2. Detrol (tolterodine) [prescribing information]. New York, NY: Pfizer; November 2016

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NEW UM PROGRAM CRITERIA			
trospium IR/ER (generic			
Program Type:	☐ Prior Authorization	☒ Quantity Limit	☐ Step Therapy

Prior Authorization Approval Criteria

trospium IR/ER (generic)

Generic name:	trospium IR/ER	
Brand name:	Sanctura (brand product has been discontinued)	
Medispan GPI:	IR 541000652003** ER 541000652070**	Y
Medication class:	Urinary Anticholinergic	
FDA-approved uses:	**Overactive Bladder**	

Usual dose range:

Overactive Bladder – IR tablets	Initial: 20mg twice daily	Maintenance: 20mg twice daily
Overactive Bladder – ER tablets	Initial: 60mg daily	Maintenance: 60mg daily

Duration of Authorization:

Ongoing: Not applicable, authorization will be ongoing for generic products.

Criteria for use for Indication #1

- 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.
- Patient is clinically diagnosed with overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency.

Criteria continuation of therapy

- Not applicable, authorization will be ongoing for generic products.

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- Patients with or at risk of uncontrolled narrow-angle glaucoma, urinary retention, gastric retention.

Not approved if:

- Patient does not meet any of the above criteria.

- Patient has a contraindication to treatment.
- Patients under the age of 18, safety and effectiveness have not been established.
- Patients with severe renal impairment (creatinine clearance [CrCl] less than 30 mL/min) (ER tablet only)

Special Considerations:

- In patients with impaired renal function (CrCl <30mL/min) – 20mg once at bedtime for IR tablets.
- Cases of angioedema involving the face, lips, tongue, and/or larynx have been reported. Immediately discontinue if tongue, hypopharynx, or larynx are involved.
- May cause drowsiness, confusion, dizziness, hallucinations, and/or blurred vision, which may impair physical or mental abilities; patients must be cautioned about performing tasks which require mental alertness (eg, operating machinery or driving).

References:

1. Sanctura [package insert]. Irvine, CA: Allergan; 2011.
2. Sanctura XR [package insert]. Irvine, CA: Allergan; September 2011.

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NEW UM PROGRAM CRITERIA			
Myrbetriq (mirabegron)			
Program Type:	☐ Prior Authorization	☒ Quantity Limit	☒ Step Therapy

Prior Authorization Approval Criteria

Myrbetriq (mirabegron)

Generic name: mirabegron
Brand name: Myrbetriq
Medispan GPI: 542000500075** MON
Medication class: Urinary Beta3 Agonist
FDA-approved uses: **Overactive bladder**
Neurogenic detrusor overactivity

Usual dose range:

Overactive bladder	Initial: 25mg once daily	Maintenance: May increase to 50 mg once daily after 4 to 8 weeks based on response and tolerability.
Neurogenic detrusor overactivity Weight 11 to <22 kg	Initial: 24 mg once daily (granules)	Maintenance: after 4 to 8 weeks of therapy, may increase dose if needed up to a maximum daily dose: 48 mg/day once daily.

Neurogenic detrusor overactivity Weight 22 to <35 kg	Initial: 32 mg once daily (granules)	Maintenance: after 4 to 8 weeks of therapy, may increase dose if needed up to a maximum daily dose: 64 mg/day once daily.
Neurogenic detrusor overactivity Weight ≥35 kg	Initial: 48 mg once daily (granules)	Maintenance: after 4 to 8 weeks of therapy, may increase dose if needed up to a maximum daily dose: 80 mg/day once daily.
Neurogenic detrusor overactivity Weight ≥35 kg	Initial: 25 mg once daily (tablets)	Maintenance: after 4 to 8 weeks of therapy, may increase dose if needed up to a maximum daily dose: 50 mg/day once daily.

Duration of Authorization:

Initial:	3 months
Ongoing:	12 months

Criteria for use for Overactive Bladder

- 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 overactive bladder in adults with symptoms of urinary frequency, urgency, or urge urinary incontinence as monotherapy or in combination with an antimuscarinic agent.
- Patient has failure, contraindication, or intolerance to at least THREE preferred generic medications:
    - Darifenacin ER
    - Oxybutynin IR/ER
    - Solifenacin
    - Tolterodine IR/ER
    - Trospium IR/ER

Criteria for use for Neurogenic detrusor overactivity

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be 3 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 neurogenic detrusor overactivity in pediatric patients ≥3 years of age (granules) and weighing ≥35 kg (tablets).
- Patient has failure, contraindication, or intolerance to generic oxybutynin IR/ER.

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. Summitted clinical documentation must be from an encounter after the start date of the current approval.
- Patient demonstrates adequate compliance as defined as an MPR >80%.

Contraindications:

- History of hypersensitivity to any of the product ingredients.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- Patients under the age of 3 years old.
- Patients with eGFR <15 mL/minute/1.73 m2 on hemodialysis
- Patients with severe hepatic impairment (Child-Pugh class C)

Special Considerations:

- In patients with impaired renal function (eGFR 15 to <30 mL/minute/1.73 m2)
  - Adults - do not exceed 25 mg once daily.
  - Pediatrics Weight ≥35 kg - Do not exceed 48 mg once daily (granules) and 25 mg once daily (tablets)
  - Pediatrics Weight 22 to <35 kg - Do not exceed 32 mg once daily (granules)
  - Pediatrics Weight 11 to <22 kg - Do not exceed 24 mg once daily (granules)
- In patients with impaired hepatic function (Child-Pugh class B)
  - Adults - do not exceed 25 mg once daily.
  - Pediatrics Weight ≥35 kg - Do not exceed 48 mg once daily (granules) and 25 mg once daily (tablets)
  - Pediatrics Weight 22 to <35 kg - Do not exceed 32 mg once daily (granules)
  - Pediatrics Weight 11 to <22 kg - Do not exceed 24 mg once daily (granules)
- Immediately discontinue and institute supportive care if the tongue, hypopharynx, or larynx is involved.
- ER granules and ER tablets are not interchangeable; do not combine products to achieve a total dose. Select appropriate product based on patient's indication and weight; ER granules are not approved for adult use (recommended dose not determined).

References:

1. Myrbetriq (mirabegron) [prescribing information]. Northbrook, IL; Astellas Pharma US Inc; March 2021.

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NEW UM PROGRAM CRITERIA			
Gemtesa (vibegron)			
Program Type:	☐ Prior Authorization	☒ Quantity Limit	☒ Step Therapy

Prior Authorization Approval Criteria

Gemtesa (vibegron)

Generic name: vibegron

Brand name:	Gemtesa	
Medispan GPI:	542000800003**	MON
Medication class:	Urinary Beta3 Agonist	
FDA-approved uses:	**Overactive Bladder**	

Usual dose range:

Overactive Bladder	Initial: 75mg once daily	Maintenance: 75mg once daily

Duration of Authorization:

Initial:	3 months
Ongoing:	12 months

Criteria for use for Overactive Bladder

- 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 overactive bladder in adults with symptoms of urinary frequency, urgency, or urge urinary incontinence as monotherapy or in combination with an antimuscarinic agent.
- Patient has failure, contraindication, or intolerance to at least THREE preferred generic medications:
    - Darifenacin ER
    - Oxybutynin IR/ER
    - Solifenacin
    - Tolterodine IR/ER
    - Trospium IR/ER

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. Summitted clinical documentation must be from an encounter after the start date of the current approval.
- Patient demonstrates adequate compliance as defined as an MPR >80%.

Contraindications:

- History of hypersensitivity to any of the product ingredients.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- Patients under the age of 18, safety and effectiveness have not been established.
- Patients with End-stage kidney disease (eGFR <15 mL/minute/1.73 m2) with or without hemodialysis.
- Patients with Severe impairment (Child-Pugh class C).

Special Considerations:

- Use with caution in patients with bladder outlet obstruction and in patients using concomitant muscarinic antagonists; may increase the risk of urinary retention. Monitor for signs and symptoms of urinary retention; discontinue use if urinary retention occurs.

References:

1. Gemtesa (vibegron) [prescribing information]. Irvine, CA: Urovant Sciences Inc; December 2020.

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NEW UM PROGRAM CRITERIA			
Detrol / Detrol LA (tolterodine IR/ER)			
Program Type:	☐ Prior Authorization	☒ Quantity Limit	☒ Step Therapy

Prior Authorization Approval Criteria

Detrol / Detrol LA (tolterodine IR/ER)

Generic name:	tolterodine IR/ER	
Brand name:	Detrol / Detrol LA	
Medispan GPI:	IR 541000602003** ER 541000602070**	MON
Medication class:	Urinary Anticholinergic	
FDA-approved uses:	**Overactive Bladder**	

Usual dose range:

Overactive Bladder – IR tablets	Initial: 2mg twice daily	Maintenance: Decrease the dosage to 1 mg twice daily based on individual response and tolerability.
Overactive Bladder – ER tablets	Initial: 4mg once daily	Maintenance: Decrease the dosage to 2 mg once daily based on individual response and tolerability.

Duration of Authorization:

Initial:	3 months
Ongoing:	12 months

Criteria for use for Overactive Bladder

- 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 overactive bladder in adults with symptoms of urinary frequency, urgency, or urge urinary incontinence as monotherapy or in combination with an antimuscarinic agent.
- Patient has failure, contraindication, or intolerance to at least THREE preferred generic medications:

- Darifenacin ER
- Oxybutynin IR/ER
- Solifenacin
- Tolterodine IR/ER
- Trospium IR/ER

-AND-

- Patient has failure, contraindication, or intolerance to one of the following medications:
  - Myrbetriq
  - Gemtesa

Criteria continuation of therapy

- Not applicable, will be ongoing for generic products.

Contraindications:

- History of hypersensitivity to any of the product ingredients or fesoterodine.
- Patients with or at risk of uncontrolled narrow-angle glaucoma, urinary retention, gastric retention.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- Patients under the age of 18, safety and effectiveness have not been established.
- Use of ER tablets is not recommended in patients with creatinine clearance less than 10 mL/min
- Use is not recommended in patients with severe hepatic impairment (Child-Pugh class C).

Special Considerations:

- In patients with impaired renal function (CrCl 10-30mL/min) 2mg per day for ER tablets, and in patients with significantly reduced renal function 1mg twice daily for IR tablets.
- In patients with impaired hepatic function (Child-Pugh class A or B) 2mg per day for ER tablets, and in patients with significantly reduced hepatic function 1mg twice daily for IR tablets.
- Cases of angioedema have been reported; some cases have occurred after a single dose. Discontinue immediately if angioedema and associated difficulty breathing, airway obstruction, or hypotension develop.
- May cause drowsiness, dizziness, and/or blurred vision, which may impair physical or mental abilities; patients must be cautioned about performing tasks which require mental alertness (eg, operating machinery or driving). Dose reduction or discontinuation should be considered if CNS effects occur.
- Has been associated with QTc prolongation at high (supratherapeutic) doses. The manufacturer recommends caution in patients with congenital prolonged QT or in patients receiving concurrent therapy with QTc-prolonging drugs (class Ia or III antiarrhythmics). However, the extent of QTc prolongation even at supratherapeutic dosages was less than 15 msec. Individuals who are CYP2D6 poor metabolizers or in the presence of inhibitors of CYP2D6 and CYP3A4 may be more likely to exhibit prolongation.

References:

1. Detrol LA (tolterodine) [prescribing information]. New York, NY: Pfizer; July 2018.
2. Detrol (tolterodine) [prescribing information]. New York, NY: Pfizer; November 2016

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NEW UM PROGRAM CRITERIA			
Ditropan XL (oxybutynin ER tablets)			
Program Type:	☐ Prior Authorization	☒ Quantity Limit	☒ Step Therapy

Prior Authorization Approval Criteria

Ditropan XL (oxybutynin ER tablets)

Generic name:	oxybutynin ER tablets	
Brand name:	Ditropan XL	
Medispan GPI:	541000452075**	MON
Medication class:	Urinary Anticholinergic	
FDA-approved uses:	**Overactive Bladder** **Neurogenic Overactive Bladder (pediatric)**	

Usual dose range:		
Overactive Bladder – ER tablets	Initial: 5-10mg once daily	Maintenance: 30mg once daily
Neurogenic Overactive Bladder (pediatric) – ER	Initial 5mg once daily	Maintenance: 20mg once daily

Duration of Authorization:

Initial:	3 months
Ongoing:	12 months

Criteria for use for Overactive Bladder

- 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.
- Patient is clinically diagnosed with overactive bladder (eg, urge urinary incontinence, urgency, frequency, urinary leakage, dysuria)
- Patient has failure, contraindication, or intolerance to at least THREE preferred generic medications:
    - Darifenacin ER
    - Oxybutynin IR/ER
    - Solifenacin
    - Tolterodine IR/ER
    - Trospium IR/ER

  -AND-
- Patient has failure, contraindication, or intolerance to one of the following medications:
    - Myrbetriq
    - Gemtesa

Criteria for use for Neurogenic Overactive Bladder (pediatric)

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be years of age or older.

- Patient is clinically diagnosed with overactive bladder due to a neurological condition (eg, spina bifida).
- Patient has failure, contraindication, or intolerance to generic oxybutynin ER tablets.

Criteria continuation of therapy

- Not applicable, authorization will be ongoing for generic products.

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- Patients with or at risk of uncontrolled narrow-angle glaucoma, urinary retention, gastric retention.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- In patients under the age of 6.

Special Considerations:

- The ER formulation consists of drug within a nondeformable matrix; following drug release/absorption, the matrix/shell is expelled in the stool. The use of nondeformable products in patients with known stricture/narrowing of the GI tract has been associated with symptoms of obstruction (rare).
- May increase the risk of this illness with intense exertion in the heat.
- Use with caution in patients with dementia treated with cholinesterase inhibitors; may aggravate symptoms of disease.

References:

1. Ditropan XL (oxybutynin chloride) extended-release tablets [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals Inc; received April 2021.

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NEW UM PROGRAM CRITERIA			
Gelnique (oxybutynin transdermal gel)			
Program Type:	☐ Prior Authorization	☒ Quantity Limit	☒ Step Therapy

Prior Authorization Approval Criteria

Gelnique (oxybutynin transdermal gel)

Generic name: oxybutynin transdermal gel
Brand name: Gelnique
Medispan GPI: 541000452040** MON
Medication class: Urinary Anticholinergic

FDA-approved uses: **Overactive Bladder**

Usual dose range:

Overactive Bladder	Initial: 1 sachet (100 mg/g) once daily	Maintenance: 1 sachet (100 mg/g) once daily

Duration of Authorization:

Initial: 3 months
Ongoing: 12 months

Criteria for use for Overactive Bladder

- 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.
- Patient is clinically diagnosed with overactive bladder (eg, urge urinary incontinence, urgency, frequency, urinary leakage, dysuria)
- Patient has failure, contraindication, or intolerance to at least THREE preferred generic medications:
    - Darifenacin ER
    - Oxybutynin IR/ER
    - Solifenacin
    - Tolterodine IR/ER
    - Trospium IR/ER

  -AND-
- Patient has failure, contraindication, or intolerance to one of the following medications:
    - Myrbetriq
    - Gemtesa

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. Summitted clinical documentation must be from an encounter after the start date of the current approval.
- Patient demonstrates adequate compliance as defined as an MPR >80%.

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- Patients with or at risk of uncontrolled narrow-angle glaucoma, urinary retention, gastric retention.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- Patients under the age of 18, safety and effectiveness have not been established.

Special Considerations:

- May increase the risk of this illness with intense exertion in the heat.
- For topical use only. Apply to clean, dry, intact skin on abdomen, thighs, or upper arms/shoulders. Rotate application sites; do not apply to the same site on consecutive days. Wash hands after use. Cover treated area with clothing after gel has dried to prevent transfer of medication to others. Do not bathe, shower, or swim until 1 hour after gel applied. Do not apply to recently shaved skin.

References:
1. Gelnique 10% (oxybutynin chloride) gel [prescribing information]. Madison, NJ: Allergan USA, Inc; March 2019.

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NEW UM PROGRAM CRITERIA			
Oxytrol (oxybutynin transdermal patchl)			
Program Type:	☐ Prior Authorization	☒ Quantity Limit	☒ Step Therapy

Prior Authorization Approval Criteria

Oxytrol (oxybutynin transdermal patchl)

Generic name: oxybutynin transdermal patch
Brand name: Oxytrol
Medispan GPI: 541000450087** MON
Medication class: Urinary Anticholinergic
FDA-approved uses: **Overactive Bladder**

Usual dose range:

Overactive Bladder	Initial: Apply one 3.9 mg/day patch twice weekly (every 3 to 4 days); change the patch on the same 2 days each week.	Maintenance: Apply one 3.9 mg/day patch twice weekly (every 3 to 4 days); change the patch on the same 2 days each week.

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

Criteria for use for Overactive Bladder

- 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.
- Patient is clinically diagnosed with overactive bladder (eg, urge urinary incontinence, urgency, frequency, urinary leakage, dysuria)
- Patient has failure, contraindication, or intolerance to at least THREE preferred generic medications:
  - Darifenacin ER
  - Oxybutynin IR/ER
  - Solifenacin
  - Tolterodine IR/ER
  - Trospium IR/ER

-AND-

- Patient has failure, contraindication, or intolerance to one of the following medications:
    - Myrbetriq
    - Gemtesa

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. Summitted clinical documentation must be from an encounter after the start date of the current approval.
- Patient demonstrates adequate compliance as defined as an MPR >80%.

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- Patients with or at risk of uncontrolled narrow-angle glaucoma, urinary retention, gastric retention.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- Patients under the age of 18, safety and effectiveness have not been established.

Special Considerations:

- May increase the risk of this illness with intense exertion in the heat.
- Apply to clean, dry, smooth (fold-free) skin on abdomen, hip, or buttock; do not apply to areas treated with oils, lotions, or powders. Do not apply to areas with cuts, scrapes, or other irritation (ie, rashes). Do not cut the patch. Apply each system at a new site (avoid reapplication to same site within 7 days). Contact with water while bathing, swimming, showering, or exercising will not change the effect; however, rubbing of the patch area should be avoided during these activities. Patch should be worn under clothing; do not expose to sunlight.

References:

1. Oxytrol for Women (oxybutynin) transdermal system [prescribing information]. Madison, NJ: Allergan USA Inc; received May 2020.

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NEW UM PROGRAM CRITERIA			
Vesicare (solifenacin tablets)			
Program Type:	☐ Prior Authorization	☒ Quantity Limit	☒ Step Therapy

Prior Authorization Approval Criteria

Vesicare (solifenacin tablets)

Generic name:	solifenacin tablets	
Brand name:	Vesicare	
Medispan GPI:	541000552003**	MON
Medication class:	Urinary Anticholinergic	
FDA-approved uses:	**Overactive Bladder**	

Usual dose range:

Overactive Bladder	Initial: 5mg once daily	Maintenance: If the 5 mg dose is well tolerated, may increase to 10 mg once daily.

Duration of Authorization:

Initial:	3 months
Ongoing:	12 months

Criteria for use for Overactive Bladder

- 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.
- Patient is clinically diagnosed with overactive bladder (eg, urge urinary incontinence, urgency, frequency, urinary leakage, dysuria)
- Patient has failure, contraindication, or intolerance to at least THREE preferred generic medications:
    - Darifenacin ER
    - Oxybutynin IR/ER
    - Solifenacin
    - Tolterodine IR/ER
    - Trospium IR/ER

  -AND-
- Patient has failure, contraindication, or intolerance to one of the following medications:
    - Myrbetriq
    - Gemtesa

Criteria continuation of therapy

- Not applicable, authorization will be ongoing for generic products

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- Patients with or at risk of uncontrolled narrow-angle glaucoma, urinary retention, gastric retention.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- Patients under the age of 18, safety and effectiveness have not been established.

Special Considerations:

- In patients with impaired renal function (CrCl <30mL/minute) – maximum of 5mg per day for adults.
- In patients with impaired hepatic function (Child-Pugh class B) – maximum of 5mg per day for adults.
- Angioedema involving the face, lips, tongue, and/or larynx have been reported; some cases have occurred after the first dose. May be life-threatening. Immediately discontinue and institute supportive care if tongue, hypopharynx, or larynx is involved.
- CNS effects have been reported (eg, headache, confusion, hallucinations, somnolence); monitor for CNS effects, particularly at treatment initiation or dose increase; reduce dose or discontinue, if necessary. May cause drowsiness and/or blurred vision, which may impair physical or mental abilities; patients must be cautioned about performing tasks that require mental alertness (eg, operating machinery, driving).
- May occur in the presence of increased environmental temperature; use caution in hot weather and/or exercise.

References:

1. VESIcare (solifenacin succinate) [prescribing information]. Northbrook, IL: Astellas Pharma US; May 2020.

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NEW UM PROGRAM CRITERIA			
Vesicare LS (solifenacin solution)			
Program Type:	☐ Prior Authorization	☒ Quantity Limit	☒ Step Therapy

Prior Authorization Approval Criteria

Vesicare LS (solifenacin solution)

Generic name: solifenacin solution
Brand name: Vesicare LS
Medispan GPI: 541000552018** MON
Medication class: Urinary Anticholinergic
FDA-approved uses: **Neurogenic detrusor overactivity**

Usual dose range:

Neurogenic detrusor overactivity – Weight 9 to 15 kg	Initial: 4mg/day	Maintenance: 4mg/day

Neurogenic detrusor overactivity – Weight >15 to 30 kg	Initial: 5mg/day	Maintenance: 5mg/day
Neurogenic detrusor overactivity – Weight >30 to 45 kg	Initial: 6mg/day	Maintenance: 6mg/day
Neurogenic detrusor overactivity – Weight >45 to 60 kg	Initial: 8mg/day	Maintenance: 8mg/day
Neurogenic detrusor overactivity – Weight > 60 kg	Initial: 10mg/day	Maintenance: 10mg/day

Duration of Authorization:

Initial:	3 months
Ongoing:	12 months

Criteria for use for Neurogenic detrusor overactivity

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be 2 years of age or older.
- Patient is clinically diagnosed with neurogenic detrusor overactivity in pediatric patients ≥2 years of age.
- Patient has failure, contraindication, or intolerance to at least THREE preferred generic medications:
    - Darifenacin ER
    - Oxybutynin IR/ER
    - Solifenacin
    - Tolterodine IR/ER
    - Trospium IR/ER

  -AND-
- Patient has failure, contraindication, or intolerance to one of the following medications:
    - Myrbetriq
    - Gemtesa

Criteria continuation of therapy

- Not applicable, authorization will be ongoing for generic products

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- Patients with or at risk of uncontrolled narrow-angle glaucoma, urinary retention, gastric retention.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- Patients under the age of 2, safety and effectiveness have not been established.
- Adult patients

Special Considerations:

- In patients with impaired renal function (eGFR 15 to <30 mL/minute/1.73 m2)

    - Pediatrics Weight 9-15 kg - Do not exceed 2mg/day
    - Pediatrics Weight >15 to 45 kg - Do not exceed 3mg/day
    - Pediatrics Weight >45 to 60 kg - Do not exceed 4mg/day
    - Pediatrics Weight >60 kg - Do not exceed 5mg/day
- In patients with impaired hepatic function (Child-Pugh class B)
    - Pediatrics Weight 9-15 kg - Do not exceed 2mg/day
    - Pediatrics Weight >15 to 45 kg - Do not exceed 3mg/day
    - Pediatrics Weight >45 to 60 kg - Do not exceed 4mg/day
    - Pediatrics Weight >60 kg - Do not exceed 5mg/day
- Angioedema involving the face, lips, tongue, and/or larynx have been reported; some cases have occurred after the first dose. May be life-threatening. Immediately discontinue and institute supportive care if tongue, hypopharynx, or larynx is involved.
- CNS effects have been reported (eg, headache, confusion, hallucinations, somnolence); monitor for CNS effects, particularly at treatment initiation or dose increase; reduce dose or discontinue, if necessary. May cause drowsiness and/or blurred vision, which may impair physical or mental abilities; patients must be cautioned about performing tasks that require mental alertness (eg, operating machinery, driving).
- May occur in the presence of increased environmental temperature; use caution in hot weather and/or exercise.
- Anaphylactic reactions have been reported rarely; may be life-threatening. Immediately discontinue therapy if anaphylactic reaction develops.

References:

1. VESIcare LS (solifenacin succinate) [prescribing information]. Northbrook, IL: Astellas Pharma US, Inc; June 2020.

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NEW UM PROGRAM CRITERIA			
Toviaz (fesoterodine)			
Program Type:	☐ Prior Authorization	☒ Quantity Limit	☒ Step Therapy

Prior Authorization Approval Criteria

Toviaz (fesoterodine)

Generic name: fesoterodine
Brand name: Toviaz
Medispan GPI: 541000202075** MON
Medication class: Urinary Anticholinergic
FDA-approved uses: **Overactive bladder**
Neurogenic detrusor overactivity

Usual dose range:

Overactive bladder	Initial: 4mg once daily	Maintenance: 8mg once daily
Neurogenic detrusor overactivity in children 6 years and older	Initial: 4mg once daily	Maintenance: 8mg once daily

Duration of Authorization:

Initial:	3 months
Ongoing:	12 months

Criteria for use for Overactive Bladder

- 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 overactive bladder in adults with symptoms of urinary frequency, urgency, or urge urinary incontinence as monotherapy or in combination with an antimuscarinic agent.
- Patient has failure, contraindication, or intolerance to at least THREE preferred generic medications:
    - Darifenacin ER
    - Oxybutynin IR/ER
    - Solifenacin
    - Tolterodine IR/ER
    - Trospium IR/ER

-AND-

- Patient has failure, contraindication, or intolerance to one of the following medications:
    - Myrbetriq
    - Gemtesa

Criteria for use for Neurogenic detrusor overactivity

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be 6 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 neurogenic detrusor overactivity in pediatric patients ≥6 years of age and weighing >25 kg.
- Patient has failure, contraindication, or intolerance to generic oxybutynin IR/ER.

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. Summitted clinical documentation must be from an encounter after the start date of the current approval.
- Patient demonstrates adequate compliance as defined as an MPR >80%.

Contraindications:

- History of hypersensitivity to any of the product ingredients, fesoterodine, or tolterodine.
- Patients with or at risk of uncontrolled narrow-angle glaucoma, urinary retention, gastric retention.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- Patients under the age of 6 years old.
- Patients with eGFR <15 mL/minute/1.73 m2 on hemodialysis
- Patients with severe hepatic impairment (Child-Pugh class C)

Special Considerations:

- In adult patients with impaired renal function (eGFR <30 mL/minute/1.73 m2) - do not exceed 4 mg once daily.
- In pediatric patients (eGFR 30 to 89 mL/minute/1.73 m2)
  - Pediatrics Weight >25 to ≤ 35 kg - Do not exceed 4mg/day
  - Pediatrics Weight >35 kg – Do not exceed 8mg/day
- In pediatric patients (eGFR 15 to 29 mL/minute/1.73 m2)
  - Pediatrics Weight >25 to ≤ 35 kg – use is not recommended
  - Pediatrics Weight >35 kg – Do not exceed 4mg/day
- Cases of angioedema involving the face, lips, tongue, and/or larynx have been reported; may be life-threatening. Cases may occur after the initial dose or after multiple doses. Discontinue immediately if tongue, hypopharynx, or larynx are involved.
- Anticholinergics may cause drowsiness, dizziness, headache, and/or blurred vision, which may impair physical or mental abilities; patients must be cautioned about performing tasks which require mental alertness (eg, operating machinery or driving). Dose reduction or discontinuation should be considered if CNS effects occur.
- May occur in the presence of increased environmental temperature; use caution in hot weather and/or exercise.

References:

1. Toviaz (fesoterodine) [prescribing information]. New York, NY: Pfizer Labs; November 2021.

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UM PROGRAM CRITERIA REVISED	
Ozempic (semaglutide injection)	
Program Type: ☒ Prior Authorization ☒ Quantity Limit ☒ Step Therapy	
Ozempic (semaglutide injection)	1. Incorporated additional criteria encouraging failure of generic antidiabetic drugs as well as acknowledging that a provider may apply a statement to confirm access outside of the benefit 2. Explicitly defined failure components for ADA treatment goals Included advice to avoid the combination of drug with dipeptidyl pertidase-4 3. Added an additional statement under continuation of therapy acknowledging that a provider may apply a statement to confirm access outside of the benefit or allow a 4-month authorization to reassess patient 4. Updated Not approved section from o Patients with type 1 diabetes, prediabetes, morbid obesity, or metabolic syndrome. -To- o Patients with Diabetes Mellitus Type 1. o If indication is limited to morbid obesity or other metabolic syndrome outside of Diabetes Mellitus Type 2. 5. Updated maximum dose to 2mg following updated dosing on package insert dated 3-29-22 from manufacturer. 6. Moved criteria for initial dosing, Rybelsus to Ozempic conversions and missed doses from criteria for use to special considerations.

Prior Authorization Approval Criteria

Ozempic (semaglutide injection)

Generic name: semaglutide injection
Brand name: Ozempic
Medispan GPI: 2717007000D2** MON
Medication class: Glucagonlike Peptide (GLP) 1 Receptor Agonist
FDA-approved uses: **Type 2 diabetes mellitus (T2DM)**
To reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease

Usual dose range:
T2DM Initial: 0.25mg weekly for 4 weeks Maintenance: 0.5-2mg weekly

Duration of Authorization:
Initial: 4 months
Ongoing: 4 months – not meeting goals (A1c >7%)
12 months – meeting goals (A1c <7%)

Estimated Cost: $12845.64 per patient per year (AWP)

Criteria for use for T2DM

- 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.
- Patient must be diagnosed with uncontrolled type 2 diabetes mellitus (defined as an A1c of 7.0% or higher)
- Patient has failure, contraindication, or intolerance to maximum therapeutic dose metformin immediate or extended release (target 2000mg total daily dose) prior to authorization. Failure is defined as not meeting ADA treatment goals (A1c > 7%) despite adequate compliance (>80% MPR) for at least the 3 months immediately prior to the request.
    - Trial and failure of a second generic antidiabetic (sulfonylureas, pioglitazone, repaglinide) is encouraged, but not required for authorization.
    - Provider may apply a statement confirming access outside of the benefit
- May be used as an adjunctive agent or alternative monotherapy for patients who fail initial therapy with lifestyle intervention and metformin or who cannot take metformin. May be preferred when weight loss is desired and/or in patients with an HbA1c relatively far from goal (eg, HbA1c 9% to 10%) and type 1 diabetes is not likely; use has not been associated with improved or worsened cardiovascular outcomes.
- Due to lack of additive glycemic benefit, use in combination with a dipeptidyl peptidase-4 inhibitor should be avoided.

Criteria for use for reduction of the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease

- 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.
- Patient must be diagnosed with both type 2 diabetes mellitus (defined as an A1c of 6.5% or higher) -AND- established cardiovascular disease defined as:
    - Coronary heart disease, manifested by myocardial infarction (MI), angina pectoris, and coronary death
    - Cerebrovascular disease, manifested by stroke and transient ischemic attack
    - Peripheral artery disease, manifested by intermittent claudication
    - Aortic atherosclerosis and thoracic or abdominal aortic aneurysm
- Risk factors of cardiovascular disease are not recognized as established cardiovascular disease including:
    - Hypercholesterolemia
    - Diabetes
    - Hypertension
    - Obesity
    - Smoking
- Patient has failure, contraindication, or intolerance to maximum therapeutic dose metformin immediate or extended release (target 2000mg total daily dose) prior to authorization. Failure is defined as not meeting ADA treatment goals (A1c > 7%) despite adequate compliance (>80% MPR) for at least the 3 months immediately prior to the request.
    - Trial and failure of a second generic antidiabetic (sulfonylureas, pioglitazone, repaglinide) is encouraged, but not required for authorization.
    - Provider may apply a statement confirming access outside of the benefit

- May be used as an adjunctive agent or alternative monotherapy for patients who fail initial therapy with lifestyle intervention and metformin or who cannot take metformin. May be preferred when weight loss is desired and/or in patients with an HbA1c relatively far from goal (eg, HbA1c 9% to 10%) and type 1 diabetes is not likely; use has not been associated with improved or worsened cardiovascular outcomes.
- Due to lack of additive glycemic benefit, use in combination with a dipeptidyl peptidase-4 inhibitor should be avoided.

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 demonstrates adequate compliance as defined as an MPR >80%.
    - Provider may apply a statement confirming access outside of the benefit or addressing correction in compliance for a 4-month authorization to reassess patients MPR.

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- History of or family history of medullary thyroid carcinoma.
- Patients with multiple endocrine neoplasia syndrome type 2.
- History of drug-induced immune-mediated thrombocytopenia.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- Patients under the age of 18 - safety and effectiveness in pediatric patients have not been established.
- As of June 2021, Wegovy was approved by the FDA for chronic weight loss. This criteria reflects the use of Ozempic for T2DM.
- Patients with Diabetes Mellitus Type 1.
- If indication is limited to morbid obesity or other metabolic syndrome outside of Diabetes Mellitus Type 2.

Special Considerations:

- The initial dose of 0.25 mg subcutaneously once weekly for 4 weeks. The lower initial dose (0.25 mg weekly) is intended to reduce GI symptoms; it does not provide effective glycemic control. After 4 weeks on the initial dose, increase to 0.5 mg subcutaneously once weekly; may increase to 1 mg once weekly after an additional 4 weeks if needed, and may increase to 2mg once weekly after an additional 4 weeks to achieve glycemic goals.
- Converting from Rybelsus to Ozempic, there is no direct equivalent to 7mg daily provided in the manufacturer's labeling; some experts convert to 0.5 mg subcutaneously once weekly, beginning the day after the last oral dose; monitor glucose more closely during transition. If the current oral dose is 14mg once daily, convert to 0.5 mg subcutaneously once weekly, beginning the day after the last oral dose.
- Missed dose should be administered as soon as possible within 5 days; resume usual schedule thereafter. If >5 days has elapsed, skip the missed dose and resume administration at the next scheduled weekly dose.
- Dose-dependent and treatment duration-dependent thyroid C-cell tumors have developed in animal studies with semaglutide therapy; it is unknown whether semaglutide will cause thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as the human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined. Patients should be counseled on the potential risk of MTC with the use of semaglutide and informed of symptoms of thyroid tumors (eg, neck mass, dysphagia, dyspnea,

persistent hoarseness). Use is contraindicated in patients with a personal or a family history of MTC and in patients with multiple endocrine neoplasia syndrome type 2 (MEN2). Cases of MTC in humans have been reported in patients treated with the glucagon-like peptide-1 (GLP-1) receptor agonist liraglutide. Consultation with an endocrinologist is recommended in patients who develop elevated calcitonin concentrations or have thyroid nodules detected during imaging studies or physical exam. Routine monitoring of serum calcitonin or using thyroid ultrasound monitoring is of uncertain value for early detection of MTC in patients treated with semaglutide.

- Cases of acute and chronic pancreatitis have been reported. It is not known if semaglutide increases risk for development of pancreatitis in patients with a history of pancreatitis; consider alternative therapy in these patients.
- Increased complications associated with diabetic retinopathy have been observed with semaglutide compared to placebo; risk may be increased in patients with a history of diabetic retinopathy at baseline. Long-term effects of semaglutide on diabetic retinopathy complications are unknown.
- According to the CDC, pen-shaped injection devices should never be used for more than one person (even when the needle is changed) because of the risk of infection. The injection device should be clearly labeled with individual patient information to ensure that the correct pen is used.
- Acute kidney injury and chronic renal failure exacerbation (including severe cases requiring hemodialysis) have been reported; some cases have been reported in patients with no known preexisting renal disease. Reports primarily occurred in patients with nausea, vomiting, diarrhea, or dehydration.
- Use of GLP-1 agonists may increase risk of gallbladder and bile duct disease. Cholelithiasis has been reported in patients treated with semaglutide; substantial or rapid weight loss may increase risk.
- Semaglutide slows gastric emptying, which may alter the absorption of other medications. Monitor narrow therapeutic index medications for increased or decreased response.
- Do not use in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis; not a substitute for insulin.
- Increased resting heart rate has been observed in placebo-controlled trials.
- Evaluate, correct, and maintain postsurgical fluid requirements and volume status prior to initiating therapy, and closely monitor the patient for the duration of therapy; acute and chronic kidney failure exacerbation may occur. A majority of cases occurred in patients with nausea, vomiting, diarrhea, and/or dehydration. Nausea is common and fluid intake may be more difficult after gastric bypass, sleeve gastrectomy, and gastric band.
- Closely monitor for efficacy and assess for signs and symptoms of pancreatitis if therapy is initiated after surgery; gastric bypass and sleeve gastrectomy (but not gastric band) significantly increase endogenous postprandial GLP-1 concentrations. Administration of exogenous GLP-1 agonists may be redundant to surgery effects.

References:

1. Ozempic (semaglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; April 2021.
2. Mechanick JI, Youdim A, Jones DB, et al. Clinical practice guidelines for the perioperative nutritional, metabolic, and nonsurgical support of the bariatric surgery patient--2013 update: cosponsored by American Association of Clinical Endocrinologists, the Obesity Society, and American Society for Metabolic & Bariatric Surgery. Surg Obes Relat Dis. 2013;9(2):159-191.[PubMed 23537696]10.1016/j.soard.2012.12.010
3. Korner J, Inabnet W, Febres G, et al. Prospective study of gut hormone and metabolic changes after adjustable gastric banding and Roux-en-Y gastric bypass. Int J Obes (Lond). 2009;33(7):786-795.[PubMed 19417773]10.1038/ijo.2009.79
4. Peterli R, Steinert RE, Woelnerhanssen B, et al. Metabolic and hormonal changes after laparoscopic Roux-en-Y gastric bypass and sleeve gastrectomy: a randomized, prospective trial. Obes Surg. 2012;22(5):740-748

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

Initial adoption: 1-1-17
Revised: 10-21-21
12-7-21
4-5-22

10-21-2021	1. Incorporated additional criteria encouraging failure of generic antidiabetic drugs as well as acknowledging that a provider may apply a statement to confirm access outside of the benefit 2. Explicitly defined failure components for ADA treatment goals Included advice to avoid the combination of drug with dipeptidyl pertidase-4 3. Added an additional statement under continuation of therapy acknowledging that a provider may apply a statement to confirm access outside of the benefit or allow a 4-month authorization to reassess patient
12-7-2021	1. Updated Not approved section from ○ Patients with type 1 diabetes, prediabetes, morbid obesity, or metabolic syndrome. To ○ Patients with Diabetes Mellitus Type 1. ○ If indication is limited to morbid obesity or other metabolic syndrome outside of Diabetes Mellitus Type 2.
4-5-2022	1. Updated maximum dose to 2mg following updated dosing on package insert dated 3-29-22 from manufacturer. 2. Moved criteria for initial dosing, Rybelsus to Ozempic conversions and missed doses from criteria for use to special considerations.
Effective Date (most recent revisions):	7-1-22

**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. Removed concomitant use of acute CGRP restriction 2. Added needle phobia to fail first criteria 3. Updated AWP to current 3-31-22 price		

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 episodic migraine.
- 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
    - 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: 9-28-21

Adopted: 9-28-21

Revised: 2-17-22

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

Effective Date (most recent revisions): 7-1-22

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

NEW UM PROGRAM CRITERIA

Quviviq (daridorexant)

Program Type:	☐ Prior Authorization	☒ Quantity Limit	☒ Step Therapy

Generic name: daridorexant
Brand name: Quviviq
Medispan GPI: 605000201003** MON
Medication class: Hypnotic, orexin receptor antagonist

FDA-approved uses: Insomnia, sleep onset or sleep maintenance

Usual dose range:

Indication #1 25 to 50 mg once daily within 30 minutes of bedtime and at least 7 hours before planned time of awakening.

Duration of Authorization:

Initial: 3 months

Ongoing: n/a

Estimated Cost: $548.40 per 30 tablets

Criteria for use for Insomnia

- 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 insomnia, characterized by difficulties with sleep onset and/or sleep maintenance, in adults.
- Patient has failure, contraindication, or intolerance to at least TWO preferred generic hypnotics
    - Eszopiclone
    - Zaleplon
    - Zolpidem

Criteria continuation of therapy

- Intended for short-term use (≤4 to 8 weeks), preferably in conjunction with nonpharmacologic therapies.
- Limit long-term use to cases for which nonpharmacologic treatments are not available or not effective and benefits are felt to outweigh risks.

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- Narcolepsy

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- Patients under the age of 18, safety and effectiveness have not been established.
- Use is not recommended in patients with severe hepatic impairment (Child-Pugh class C).

Special Considerations:

- In patients with impaired hepatic function (Child-Pugh class B) a maximum 25 mg/day is recommended.
- 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, driving). Next-day somnolence may occur when taken as prescribed. Daytime driving impairment risk increases when taken with less than a full night's sleep, and/or when a higher than recommended dose is taken. CNS depression may increase the risk of falls, particularly in older adults. CNS depression may persist for several days following discontinuation of therapy.
- Complex sleep behaviors, including sleep walking, sleep driving, preparing and eating food, making phone calls, or having sex while not fully awake, may occur following use of daridorexant. Patients usually do not remember these events. May occur with first use or any subsequent use with or without the use of alcohol or other CNS depressants. Discontinue immediately if a patient experiences a complex sleep behavior.
- Sleep paralysis (inability to move or speak for up to several minutes during sleep-wake transitions), hypnagogic/hypnopompic hallucinations, and mild cataplexy may occur. Cataplexy symptoms may include periods of leg weakness lasting from seconds to a few minutes, can occur both at night and during the day, and may not be associated with a triggering event (eg, laughter, surprise).
- Use with caution in patients with depression; worsening of depression, including suicide or suicidal ideation, has been reported with the use of hypnotics.
- Use with caution in patients with respiratory compromise; has not been studied in patients with moderate obstructive sleep apnea (OSA) requiring continuous positive airway pressure, severe OSA, or severe chronic obstructive pulmonary disease.
- Use with caution due to increased risk of somnolence, fatigue, drowsiness, and falls.
- Symptomatic treatment of insomnia should be initiated only after careful evaluation of potential causes of sleep disturbance. Failure of sleep disturbance to resolve after 7 to 10 days may indicate psychiatric and/or medical illness.

References:

1. Quviviq (daridorexant) [prescribing information]. Radnor, PA: Idorsia Pharmaceuticals US Inc; January 2022.
2. Mignot E, Mayleben D, Fietze I, et al; investigators. Safety and efficacy of daridorexant in patients with insomnia disorder: results from two multicentre, randomised, double-blind, placebo-controlled, phase 3 trials. Lancet Neurol. 2022;21(2):125-139. doi:10.1016/S1474-4422(21)00436-1[PubMed 35065036]
3. Roch C, Bergamini G, Steiner MA, Clozel M. Nonclinical pharmacology of daridorexant: a new dual orexin receptor antagonist for the treatment of insomnia. Psychopharmacology (Berl). 2021;238(10):2693-2708. doi:10.1007/s00213-021-05954-0[PubMed 34415378]
4. Qaseem A, Kansagara D, Forciea MA, Cooke M, Denberg TD; Clinical Guidelines Committee of the American College of Physicians. Management of chronic insomnia disorder in adults: a clinical practice guideline from the American College of Physicians. Ann Intern Med. 2016;165(2):125-133. doi:10.7326/M15-2175[PubMed 27136449]
5. Winkelman JW. Overview of the treatment of insomnia in adults. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com. Accessed January 18, 2022.
6. Sateia MJ, Buysse DJ, Krystal AD, Neubauer DN, Heald JL. Clinical practice guideline for the pharmacologic treatment of chronic insomnia in adults: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2017;13(2):307-349. doi:10.5664/jcsm.6470[PubMed 27998379]

MedOne P&T Committee approval: Date: 5-19-22

Initial adoption: 5-19-22
Revised: -22
5-19-22 1. Pricing updated based off of AWP (5-19-22)
Effective Date (most recent revisions): 7-1-22

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

NEW UM PROGRAM CRITERIA			
Scemblix - asciminib			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy

Prior Authorization Approval Criteria

Scemblix – asciminib

Generic name: asciminib
Brand name: Scemblix
Medication class: BCR-ABL Tyrosine Kinase Inhibitor / STAMP Inhibitor
FDA-approved uses: Chronic myeloid leukemia, Philadelphia chromosome-positive (Ph+), chronic phase, previously treated with ≥2 tyrosine kinase inhibitors

Chronic myeloid leukemia, Ph+, chronic phase, with T315I mutation

Usual dose range:

Chronic myeloid leukemia, Philadelphia chromosome-positive (Ph+), chronic phase, previously treated with ≥2 tyrosine kinase inhibitors	Oral: 80 mg once daily or 40 mg twice daily (Rea 2021) until treatment failure or unacceptable toxicity.
Chronic myeloid leukemia, Ph+, chronic phase, with T315I mutation	Oral: 200 mg twice daily until treatment failure or unacceptable toxicity.

Duration of Authorization:

Initial:	3 months
Ongoing:	3 months

Criteria for use for chronic myeloid leukemia, Philadelphia chromosome-positive (Ph+), chronic phase, previously treated with ≥2 tyrosine kinase inhibitors

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan
- Patient is at least 18 years of age
- Patient has a formal diagnosis of Chronic myeloid leukemia, Philadelphia chromosome-positive (Ph+), chronic phase
- Patient has tried and failed at least 2 tyrosine kinase inhibitors (imatinib, bosutinib, dasatinib, nilotinib, ponatinib)

Criteria for use for Chronic myeloid leukemia, Ph+, chronic phase, with T315I mutation

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan
- Patient is at least 18 years of age

- Patient has laboratory confirmation of T3151 mutation (results from an approved lab must be submitted for review)

Criteria continuation of therapy:

- Patient must be achieving clinical benefit from the treatment without unacceptable toxicity
- Patient has demonstrated a minimum medication possession ratio of at least 80% unless clinical rational is provided to justify holding treatment
- Patients' CBC, serum lipase and amylase levels are measured periodically during treatment and within normal limits
- Patient has not experienced disease progression or unacceptable toxicity

Contraindications:

- History of hypersensitivity to any of the product ingredients

Not approved if:

- Patient has uncontrolled hypertension (Stage 1 – Systolic 130 to 139 mmHg or diastolic 80 to 89 mmHg; Stage 2 – Systolic >140 mmHg or diastolic > 90 mmHg)
- Dose requested exceeds the FDA approved maximum dose for the indication

Special considerations:

- Cardiovascular toxicity (eg, ischemic cardiac and CNS conditions, arterial thrombotic and embolic conditions), including Grade 3 and Grade 4 events, has been reported. Monitoring is required and dose reduction, interruption, or permanent discontinuation may be necessary
- Myelosuppression (eg, neutropenia, thrombocytopenia, anemia) has been reported. Monitoring is required and dose reduction, interruption, or permanent discontinuation may be necessary
- Pancreatitis has been reported. Monitoring is required and dose reduction, interruption, or permanent discontinuation may be necessary
- Hypersensitivity reactions, including Grade 3 and Grade 4 events, have been reported. Monitoring is required and dose reduction, interruption, or permanent discontinuation may be necessary
- May cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment and for 1 week after the last dose

References:

1. Scemblix Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; November 2021
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/.

MedOne Clinical Review Board approval: Date: 5/12/2022

Adopted:
Revised :

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

NEW UM PROGRAM CRITERIA			
Tavneos (avacopan)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☐ Step Therapy

Prior Authorization Approval Criteria

Tavneos (avacopan)

Generic name: avacopan
Brand name: Tavneos
Medication class: Complement C5a Receptor Inhibitor
FDA-approved uses: To treat severe active anti-neutrophil cytoplasmic autoantibody-associated vasculitis (ANCA-associated vasculitis) (granulomatosis with polyangiitis and microscopic polyangiitis) in combination with standard therapy, including glucocorticoids

Usual dose range:

ANCA-associated vasculitis	30mg twice daily

Duration of Authorization:

Initial:	3 months
Ongoing:	12 months

Criteria for use for indication #1

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan
- Patient is at least 18 years of age
- Patient has a diagnosis of granulomatosis with polyangiitis or microscopic polyangiitis
- Patient is positive for proteinase 3 antibodies, myeloperoxidase antibodies, or anti-neutrophil cytoplasmic autoantibody
- Patient is using as adjunct therapy, confirmed in the submitted treatment plan, to at least one immunosuppressant treatment (methotrexate, azathioprine, rituximab, mycophenolate, cyclophosphamide)
- Documentation of baseline Birmingham vasculitis activity score, eGFR, and urinary albumin creatinine ratio must be submitted for review
- Medication is prescribed by, or in consultation with, a board-certified rheumatologist, nephrologist, or immunologist
- Dose limited to a maximum of 30 mg twice daily (6 capsules per day)
- Must have a negative Hepatitis B virus screening in the prior 3 months to starting treatment

Criteria continuation of therapy:

- Patient must be achieving clinical benefit from the treatment without unacceptable toxicity
- Patient has demonstrated a minimum medication possession ratio of at least 80% unless clinical rational is provided to justify holding treatment

- Patient has achieved an objective measure of improvement from baseline, including improvement in eGFR, urinary albumin creatinine ratio, Birmingham Vasculitis Activity Score, as compared to baseline
- Patient has achieved a subjective measure of improvement in at least one patient symptom (joint pain, myalgia, cough, abdominal pain, ulcers)

Contraindications:

- History of hypersensitivity to any of the product ingredients

Not approved if:

- Patient has disease remission/inactive disease
- Patient has active, untreated and/or uncontrolled chronic liver disease
- patient has active, serious infection, including localized infections

Special considerations:

- Serious cases of hepatic injury, including serious and life-threatening cases of transaminase elevations and hepatobiliary events, have been reported; initial screening and monitoring recommended. Therapy interruption or discontinuation may be necessary
- Angioedema, including cases that required hospitalization, has been reported; discontinuation of therapy and supportive care required. Restarting of therapy not recommended unless another cause established
- Serious, including fatal, infections have been reported; close monitoring recommended. Treatment interruption and antimicrobial therapy may be required
- In patients with chronic or recurrent infection, who have been exposed to tuberculosis, those with a history of a serious or an opportunistic infection, who have resided or traveled in areas of endemic tuberculosis or endemic mycoses, or those with underlying conditions that may predispose them to infection, consider risk and benefits of therapy prior to initiating

References:

1. Tavneos [prescribing information]. Cincinnati, OH: ChemoCentryx; October 2021.
2. Chung S, Langford CA, Maz M, et al. 2021 American College of Rheumatology/Vasculitis Foundation guidelines for the management of antineutrophil cytoplasmic antibody-associated vasculitis. Arthritis Care and Research. 2021; 73(8):1088-1105.
3. Merkel PA, Jayne DR, Wang C, Hillson J, and Bekker P. Evaluation of the safety and efficacy of avacopan, a C5a receptor inhibitor, in patients with antineutrophil cytoplasmic antibody-associated vasculitis treated concomitantly with rituximab or cyclophosphamide/azathioprine: protocol for a randomized, double-blind, active-controlled, phase 3 trial. JMIR Res Protoc. 2020; 9(4):e16664 doi: 10.2196/16664:10.2196/16664.

MedOne Clinical Review Board approval: Date: 5/12/2022

Adopted:
Revised :

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

NEW UM PROGRAM CRITERIA			
Voxzogo – vosoritide			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☐ Step Therapy

Prior Authorization Approval Criteria

Voxzogo – vosoritide

Generic name: vosoritide
Brand name: Voxzogo
Medication class: C-type Natriuretic Peptide
FDA-approved uses: Achondroplasia

Usual dose range:

Improve growth in children five years of age and older with achondroplasia and open epiphyses	SUBQ: 0.24mg-0.8mg daily based on patient actual body weight

Duration of Authorization:

Initial:	3 months
Ongoing:	6 months

Criteria for use for Achondroplasia

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan
- Patient is at least 5 years of age and less than 18 years of age
- Genetic testing confirming diagnosis of achondroplasia must be submitted for review (mutation identified in the fibroblast growth factor receptor type 3 gene)
- Patient's epiphyses are open
- Baseline annual growth velocity exceeds 1.5 cm/year
- Medication is prescribed by a board-certified pediatric endocrinologist
- Current weight and height must be submitted

Criteria continuation of therapy:

- Patient must be achieving clinical benefit from the treatment without unacceptable toxicity
- Patient has demonstrated a minimum medication possession ratio of at least 80% unless clinical rational is provided to justify holding treatment
- Body weight and growth velocity must be submitted for review every 6 months
- Patients' growth velocity exceeds their baseline annualized growth velocity value

Contraindications:

- History of hypersensitivity to any of the product ingredients

Not approved if:

- Further growth potential is unlikely, as confirmed by closure of epiphyses
- Patient has an eGFR < 60 mL/min/1.73m2
- Patient has had, or is expected to have limb-lengthening surgery
- Patient is currently taking growth-hormone products

Special considerations:

- Cardiovascular: Transient decreases in blood pressure may occur
- Voxzogo has not been evaluated in patients with renal impairment and therefore, is not recommended for patients with eGFR < 60 mL/min/1.73m2

References:

1. Voxzogo™ subcutaneous injection [prescribing information]. Novato, CA: BioMarin; November 2021
2. National Organization for Rare Disorders (NORD). 2021. Available at: Achondroplasia - NORD (National Organization for Rare Disorders) (rarediseases.org).
3. Zhou S, Pauli R M. Achondroplasia. National Organization for Rare Disorders (NORD). https://rarediseases.org/rare-diseases/achondroplasia/.
4. Micromedex [online database]. Available at www.micromedexsolutions.com.

MedOne Clinical Review Board approval: Date: 5/12/2022

Adopted:
Revised :

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