COUPE HEALTH

PHARMACY UTILIZATION MANAGEMENT (UM) PROGRAM CRITERIA ACTIVITY

Provider Notification

Policies Effective: 11/7/2022 Notification Posted: September 23, 2022

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

UM PROGRAM CRITERIA REVISED			
Linzess (linaclotide)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy
Linzess	1. Removed Zelnorm as a fail first medication, as it has been removed from the US market 6-30-22. 2. Updated "Chart notes evaluating the safety and efficacy from within the prior 12 months are required for reauthorization." in continuation criteria to "Updated chart notes or other clinical documentation confirming efficacy and tolerability of the requested treatment will be required for all renewal reviews. Submitted clinical documentation must be from an encounter after the start date of the current approval." 3. AWP price current as of 9-15-22		

Prior Authorization Approval Criteria

Linzess (linaclotide)

Generic name: linaclotide
Brand name: Linzess
Medication class: guanylate cyclase-C agonist
FDA-approved uses: Chronic idiopathic constipation (CIC)
Irritable bowel syndrome with constipation (IBS-C)

Usual dose range:
CIC 72-145mcg
IBS 290mcg

Duration of Authorization:

Initial:	3 months
Ongoing:	12 months

Estimated Cost: $7163.25/yr (AWP)

Criteria for use for chronic idiopathic constipation

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Patient is 18 years or older, safety and efficacy in pediatric patients have not been established.
- Clinically diagnosed chronic idiopathic constipation, defined as less than 3 SBMs (spontaneous bowel movements) per week, on average, with one or more of the following symptoms of constipation for at least 6 months:
    - Very hard stools for at least a quarter of all bowel movements
    - Sensation of incomplete evacuation following at least a quarter of all bowel movements
    - Straining with defecation at least a quarter of the time
- Patient has failure, contraindication, or intolerance to 3 standard laxative classes:
    - Bulk forming laxative (psyllium, inulin, wheat dextrin, methylcellulose, polycarbophil)
    - Osmotic laxative (lactulose, polyethylene glycol (Miralax))
    - Stimulant laxative (cascara, senna, bisacodyl, castor oil)
    - Saline laxative (Fleet Phospho-Soda, milk of magnesia, magnesium citrate)
- Patient is not concomitantly taking Amitiza, Motegrity, or Trulance.

Criteria for use for irritable bowel syndrome with constipation

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Patient is 18 years or older, safety and efficacy in pediatric patients have not been established.
- Clinically diagnosed irritable bowel syndrome, defined as abdominal pain or discomfort occurring over at least 6 months with two or more of the following:
    - Relieved with defecation
    - Onset associated with a change in stool frequency
    - Onset associated with a change in stool form
- Patient has failure, contraindication, or intolerance to 3 standard laxative classes:
    - Bulk forming laxative (psyllium, inulin, wheat dextrin, methylcellulose, polycarbophil)
    - Osmotic laxative (lactulose, polyethylene glycol (Miralax))
    - Stimulant laxative (cascara, senna, bisacodyl, castor oil)
    - Saline laxative (Fleet Phospho-Soda, milk of magnesia, magnesium citrate)
- Patient is not concomitantly taking Amitiza or Trulance.

Criteria continuation of therapy

- Patient is tolerating and responding to medication and there continues to be a medical need for the medication.
- Updated chart notes or other clinical documentation confirming efficacy and tolerability of the requested treatment will be required for all renewal reviews. Submitted clinical documentation must be from an encounter after the start date of the current approval.
- Patient demonstrates adequate compliance as defined as an MPR >80%.

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- Pediatric patients younger than 6 years
- Mechanical GI obstruction (known or suspected).

Not approved if:

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

Special Considerations:

- Administer at least 30 minutes before the first meal of the day on an empty stomach. Loose stools and greater stool frequency may occur after administration with a high-fat breakfast.

References:

1. Linzess (linaclotide) [prescribing information]. Madison, NJ: Allergan USA, Inc; April 2021.

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

Initial adoption:	1-1-17
Revised:	8-27-21 8-26-22
8-27-21	1. Changed initial and ongoing duration 2. Reduced try/fail criteria from 4 to 3
8-26-22	1. Removed Zelnorm as a fail first medication, as it has been removed from the US market 6-30-22. 2. Updated "Chart notes evaluating the safety and efficacy from within the prior 12 months are required for reauthorization." in continuation criteria to "Updated chart notes or other clinical documentation confirming efficacy and tolerability of the requested treatment will be required for all renewal reviews. Submitted clinical documentation must be from an encounter after the start date of the current approval." 3. AWP price current as of 9-15-22
Effective Date (most recent revisions):	11-7-22

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

Prior Authorization Approval Criteria

Migranal (dihydroergotamine)

Generic name:	dihydroergotamine	
Brand name:	Migranal	
Medispan GPI	670000301020**	MON
Medication class:	**Antimigraine Agent; Ergot Derivative**	
FDA-approved uses:	**Acute treatment of migraine**	

Usual dose range:

Acute Treatment	One spray (0.5 mg) into each nostril; repeat after 15 minutes (total of 4 sprays per dose). Maximum of 4 sprays (1 dose) per 24 hours; safety of doses >8 sprays (2 doses)/week has not been established.

Duration of Authorization:

Initial:	3 months
Ongoing:	12 months

Estimated Cost: $4587.52 per package (8 sprays) (AWP)

Criteria for use for Acute Treatment

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

    -AND-
    - At least ONE:
        - Acute CGRP
            - Nurtec ODT
            - Reyvow
            - Ubrelvy
        - Non-Oral Triptan (Nasal spray and Injection)
            - Zomig Nasal Spray
            - Imitrex STAT Dose

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

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

- Quantity limit of 1 package (8 sprays) per month.

Criteria continuation of therapy

- Patient is tolerating and responding to medication and there continues to be a medical need for the medication.
- Updated chart notes or other clinical documentation confirming efficacy and tolerability of the requested treatment will be required for all renewal reviews. Submitted clinical documentation must be from an encounter after the start date of the current approval.

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.
- Not intended for the prophylactic therapy of migraine or for the management of hemiplegic migraine or migraine with brainstem aura (basilar migraine).

Special Considerations:

- Dihydroergotamine has been associated with cardiac valvular fibrosis; usually associated with long-term, frequent use or in combination with other medications associated with cardiac valvular fibrosis.
- Adverse cardiac events, including acute myocardial infarction, life-threatening disturbance of cardiac rhythm, and death have been rarely reported following use of dihydroergotamine. May cause vasospastic reactions associated with symptoms of muscle pains, numbness, coldness, pallor, and cyanosis of the digits; myocardial, colonic, and peripheral vascular ischemia have been reported. In patients with compromised circulation, persistent vasospasm may result in gangrene or death. Evaluate patients who experience signs or symptoms suggestive of angina following administration for the presence of coronary artery disease (CAD) or a predisposition to variant angina before receiving additional doses. Similarly, evaluate patients who experience other symptoms or signs suggestive of decreased arterial flow, such as ischemic bowel syndrome or Raynaud syndrome. Discontinue therapy if patients develop symptoms of vasoconstriction. Significant hypertension has been reported (rarely) in patient with and without a history of hypertension.
- Cerebral hemorrhage, subarachnoid hemorrhage, and stroke have occurred (in some cases resulted in fatalities) following use of dihydroergotamine. Discontinue therapy if a cerebrovascular event is suspected.
- Rare cases of pleural and/or retroperitoneal fibrosis have been reported with prolonged daily use.
- Screen patients for risk factors for CAD (eg, hypertension, hypercholesterolemia, smoker, obesity, diabetes, strong family history of CAD, postmenopausal patients, males who are >40 years of age) prior to initiation of therapy; perform a cardiovascular evaluation in patients with CAD risk factors being initiated on dihydroergotamine injection or 0.5 mg/spray nasal spray. Perform cardiovascular evaluation regardless of CAD risk factors in patients initiated on 0.725 mg/spray nasal spray. If evaluation reveals coronary artery vasospasm or myocardial ischemia, do not initiate therapy. If evaluation does not reveal coronary artery disease, ischemic myocardial disease, or other significant cardiovascular disease, administer the first dose in an adequately equipped facility unless the patient has previously received dihydroergotamine without cardiovascular complications. ECG monitoring is recommended in patients with CAD risk factors.

References:

2. Migranal (dihydroergotamine mesylate) [prescribing information]. Bridgewater, NJ: Bausch Health US LLC; April 2022.
3. The Institute for Clinical Systems Improvement Work Group. Health Care Guideline: Diagnosis and Treatment of Headache. 9th ed. Bloomington, MN: The Institute for Clinical Systems Improvement,

2009. http://www.icsi.org/guidelines_and_more/gl_os_prot/other_health_care_conditions/headache/headache__diagnosis_and_treatment_of__guideline_.html.
4. Matchar DB, Young WB, Rosenberg JH, et al for the US Headache Consortium. Evidence-based guidelines for migraine headache in the primary care setting: pharmacological management of acute attacks. Saint Paul, MN: American Academy of Neurology; 2000. http://www.aan.com/professionals/practice/pdfs/gl0087.pdf.
5. Gallagher RM; Dihydroergotamine Working Group. Acute treatment of migraine with dihydroergotamine nasal spray. Arch Neurol. 1996;53(12):1285-1291. doi:10.1001/archneur.1996.00550120097022[PubMed 8970458]

MedOne P&T Committee approval: Date: 9-15-2022

Adopted:	9-15-22
Revised:	
Updates:	
7-15-22	AWP price current as of 9-15-22
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NEW UM PROGRAM CRITERIA			
Opzelura (ruxolitinib)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy

Prior Authorization Approval Criteria

Opzelura (ruxolitinib)

Generic name:	ruxolitinib
Brand name:	Opzelura
Medispan GPI:	902720605037 **MON**
Medication class:	Janus kinase (JAK) inhibitor
FDA-approved uses:	**Atopic dermatitis** **Nonsegmental vitiligo**

Usual dose range:

Atopic dermatitis	Apply a thin layer to affected area(s) twice daily; application area should not exceed 20% BSA.
Nonsegmental vitiligo	Apply a thin layer to affected area(s) twice daily; application area should not exceed 10% BSA.

Duration of Authorization:

Initial:	4 months
Ongoing:	1 year

Estimated Cost: $28,080/12 months AWP (1x 60gm tube per month)

Criteria for use for Atopic dermatitis

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be 12 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 mild to moderate atopic dermatitis, consistent with any one of the following score tools: IGA, EASI, POEM, or SCORAD (results from the evaluation tool must be submitted with the clinical documentation).
    - IGA = 0 (clear), 1 (almost clear), 2 (mild), 3 (moderate), and 4 (severe)
    - EASI = 0 (clear), 0.1 – 1.0 (almost clear), 1.1 – 7.0 (mild), 7.1 – 21.0 (moderate), 21.1 – 50.0 (severe), 50.1 – 72.0 (very severe)
    - POEM = 0 – 2 (clear or almost clear), 3 – 7 (mild), 8 – 16 (moderate), 17 – 24 (severe), 25 – 28 (very severe)
    - SCORAD = <25 (mild), 25 to 50 (moderate), >50 (severe)
- Must be prescribed by, or in consultation with a board-certified dermatologist or an allergist/immunologist.
- Patient has atopic dermatitis involvement not to exceed 20% of BSA
- Patient has failure (for at least 30 consecutive days), contraindication, or intolerance to:
    - at least TWO of the following topical medication classes:
        - Topical corticosteroid (desonide, mometasone furoate, fluocinolone acetonide, fluocinonide)
        - Topical calcineurin inhibitor [Elidel (pimecrolimus), Protopic (tacrolimus)]
        - Eucrisa (crisaborole)

      -AND-
    - at least ONE generic preferred systemic agents:
        - oral corticosteroids
        - oral cyclosporine
        - oral azathioprine
        - oral methotrexate
        - oral mycophenolate mofetil
- Therapy should be discontinued when signs/symptoms resolve. Reassess therapy if signs/symptoms have not resolved within 8 weeks.

Criteria for use for Nonsegmental vitiligo

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be 12 years of age or older.
- Grandfather criteria allowed in plans with coverage for cosmetic indications
    - Please see policy and procedure "*14 – Grandfather Status Authorization*" for additional information.
- Patient is clinically diagnosed with nonsegmental vitiligo
- Must be prescribed by, or in consultation with a board-certified dermatologist
- Patient has failure, contraindication, or intolerance to:
    - at least TWO of the following topical medication classes:
        - Topical corticosteroid (desonide, mometasone furoate, fluocinolone acetonide, fluocinonide)
        - Topical calcineurin inhibitor [Elidel (pimecrolimus), Protopic (tacrolimus)]

      -AND-
    - at least ONE generic preferred systemic agents:
        - oral corticosteroids
- Therapy should be reassessed for continued therapy if no meaningful improvement with re-pigmentation by 24 weeks.

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.

Special Considerations:

- Hematologic toxicity, including thrombocytopenia, anemia, and neutropenia, may occur.
- Consider risks versus benefits prior to initiating or continuing topical ruxolitinib in patients with current or history of malignancy (except successfully treated nonmelanoma skin cancer) or in smokers (current or past; smoking increases risk of malignancy).
- Nonmelanoma skin cancers (basal cell and squamous cell carcinoma) have been reported in patients treated with topical ruxolitinib. Minimize exposure to sunlight and UV light (eg, wear protective clothing, apply sunscreen).

References:

6. Opzelura (ruxolitinib) [prescribing information]. Wilmington, DE: Incyte Corporation; July 2022.
7. Papp K, Szepietowski JC, Kircik L, et al. Efficacy and safety of ruxolitinib cream for the treatment of atopic dermatitis: results from 2 phase 3, randomized, double-blind studies. J Am Acad Dermatol. 2021;85(4):863-872. doi:10.1016/j.jaad.2021.04.085[PubMed 33957195]
8. Gong X, Chen X, Kuligowski ME, et al. Pharmacokinetics of ruxolitinib in patients with atopic dermatitis treated with ruxolitinib cream: data from phase II and III studies. Am J Clin Dermatol. 2021;22(4):555-566. doi:10.1007/s40257-021-00610-x[PubMed 33982267]

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Initial adoption: 9-15-22
Revised:
9-15-22 1. Pricing updated based off of AWP (9-15-22)
Effective Date (most recent revisions): 11-7-2022

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

Prior Authorization Approval Criteria

Trudhesa (dihydroergotamine)

Generic name: dihydroergotamine
Brand name: Trudhesa
Medispan GPI 670000301134** MON
Medication class: **Antimigraine Agent; Ergot Derivative**
FDA-approved uses: **Acute treatment of migraine**

Usual dose range:

Acute Treatment	One spray (0.725 mg) into each nostril (total of 2 sprays per dose), may repeat as needed after ≥1 hour for a total of 4 sprays (2 doses). Maximum of Four sprays (2 doses)/24 hours; 6 sprays (3 doses)/7 days.

Duration of Authorization:

Initial:	3 months
Ongoing:	12 months

Estimated Cost: $1071 per package (4 sprays) (AWP)

Criteria for use for Acute Treatment

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

    -AND-
    - At least ONE:
        - Acute CGRP
            - Nurtec ODT
            - Reyvow
            - Ubrelvy
        - Non-Oral Triptan (Nasal spray and Injection)
            - Zomig Nasal Spray
            - Imitrex STAT Dose
- In patients with 4 or more migraines per month (per AAFP guidelines), patient is required to be concurrently managed on a migraine preventative therapy, unless otherwise clinically inappropriate to use a preventative therapy. Generic preferred agents include:
    - Amitriptyline (Elavil)
    - Beta-Blockers (Metoprolol, Propranolol, Nadolol)
    - Botox (may require specialty drug review with fail first requirements)
    - CGRP approved for preventative treatment (may require drug review with fail first requirements)
    - Divalproex Sodium (Depakote, Depakote ER)
    - Sodium Valproate (Depakene, Depacon)
    - Topiramate (Topamax)
    - Gabapentin (Neurontin
    - Venlafaxine (Effexor)
    - Verapamil

    Certain preventative therapies may require have additional step-therapy, clinical review, and quantity limit requirements.
- Quantity limit of 1 package (4 sprays) per month.

Criteria continuation of therapy

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

Contraindications:

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

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- Not intended for the prophylactic therapy of migraine or for the management of hemiplegic migraine or migraine with brainstem aura (basilar migraine).

Special Considerations:

- Dihydroergotamine has been associated with cardiac valvular fibrosis; usually associated with long-term, frequent use or in combination with other medications associated with cardiac valvular fibrosis.
- Adverse cardiac events, including acute myocardial infarction, life-threatening disturbance of cardiac rhythm, and death have been rarely reported following use of dihydroergotamine. May cause vasospastic reactions associated with symptoms of muscle pains, numbness, coldness, pallor, and cyanosis of the digits; myocardial, colonic, and peripheral vascular ischemia have been reported. In patients with compromised circulation, persistent vasospasm may result in gangrene or death. Evaluate patients who experience signs or symptoms suggestive of angina following administration for the presence of coronary artery disease (CAD) or a predisposition to variant angina before receiving additional doses. Similarly, evaluate patients who experience other symptoms or signs suggestive of decreased arterial flow, such as ischemic bowel syndrome or Raynaud syndrome. Discontinue therapy if patients develop symptoms of vasoconstriction. Significant hypertension has been reported (rarely) in patient with and without a history of hypertension.
- Cerebral hemorrhage, subarachnoid hemorrhage, and stroke have occurred (in some cases resulted in fatalities) following use of dihydroergotamine. Discontinue therapy if a cerebrovascular event is suspected.
- Rare cases of pleural and/or retroperitoneal fibrosis have been reported with prolonged daily use.
- Screen patients for risk factors for CAD (eg, hypertension, hypercholesterolemia, smoker, obesity, diabetes, strong family history of CAD, postmenopausal patients, males who are >40 years of age) prior to initiation of therapy; perform a cardiovascular evaluation in patients with CAD risk factors being initiated on dihydroergotamine injection or 0.5 mg/spray nasal spray. Perform cardiovascular evaluation regardless of CAD risk factors in patients initiated on 0.725 mg/spray nasal spray. If evaluation reveals coronary artery vasospasm or myocardial ischemia, do not initiate therapy. If evaluation does not reveal coronary artery disease, ischemic myocardial disease, or other significant cardiovascular disease, administer the first dose in an adequately equipped facility unless the patient has previously received dihydroergotamine without cardiovascular complications. ECG monitoring is recommended in patients with CAD risk factors.

References:

9. Trudhesa (dihydroergotamine mesylate) [prescribing information]. Seattle, WA: Impel NeuroPharma Inc; September 2021.
10. The Institute for Clinical Systems Improvement Work Group. Health Care Guideline: Diagnosis and Treatment of Headache. 9th ed. Bloomington, MN: The Institute for Clinical Systems Improvement, 2009. http://www.icsi.org/guidelines_and_more/gl_os_prot/other_health_care_conditions/headache/headache__diagnosis_and_treatment_of__guideline_.html.
11. Matchar DB, Young WB, Rosenberg JH, et al for the US Headache Consortium. Evidence-based guidelines for migraine headache in the primary care setting: pharmacological management of acute attacks. Saint Paul, MN: American Academy of Neurology; 2000. http://www.aan.com/professionals/practice/pdfs/gl0087.pdf.
12. Gallagher RM; Dihydroergotamine Working Group. Acute treatment of migraine with dihydroergotamine nasal spray. Arch Neurol. 1996;53(12):1285-1291. doi:10.1001/archneur.1996.00550120097022[PubMed 8970458]

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