COUPE HEALTH

PHARMACY UTILIZATION MANAGEMENT (UM) PROGRAM CRITERIA ACTIVITY

Provider Notification

Policies Effective: November 1st, 2022 Notification Posted: September 6th, 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			
Amitiza (lubiprostone)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy
Amitiza	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."		

Prior Authorization Approval Criteria

Amitiza (lubiprostone)

Generic name: lubiprostone
Brand name: Amitiza
Medication class: Chloride channel activator
FDA-approved uses: Chronic idiopathic constipation (CIC)
Irritable bowel syndrome with constipation (IBS-C) in women
Opioid-induced constipation (OIC)

Usual dose range:

CIC	24mcg twice daily
IBS	8mcg twice daily
OIC	24mcg twice daily

Duration of Authorization:

Initial:	3 months
Ongoing:	12 months

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 has failure, contraindication, or intolerance to Linzess.
- Patient is not concomitantly taking Linzess, 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.
- Patient was born female.
- 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 has failure, contraindication, or intolerance to Linzess.
- Patient is not concomitantly taking Linzess or Trulance.

Criteria for use for opioid-induced 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.
- Patient has OIC and chronic non-cancer pain

- Patient has chronic use of an opioid agent in the past 30 days
- 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 has failure, contraindication, or intolerance to Movantik.
- Will not be used concomitantly with other opioid antagonists.
- Patient is not concomitantly taking Movantik or Symproic.

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.
- Mechanical GI obstruction (known or suspected).

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- Not approved for use in males with irritable bowel syndrome with constipation.

Special Considerations:

- Effectiveness of Amitiza in the treatment of opioid-induced constipation in patients taking diphenylheptane opioids (e.g., methadone) has not been established.
- Patients with moderate to severe hepatic impairment (Child-Pugh class B or C) have higher systemic drug exposure; dosage adjustment may be recommended, depending on the indication and severity of hepatic impairment.

References:

1. Amitiza (lubiprostone) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America, Inc; November 2020.

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

Initial adoption:	1-1-17
Revised:	8-27-21
	8-26-22
8-27-21	Changed initial and ongoing duration Reduced try/fail criteria from 4 to 3 Added Linzess/Movantik trials
8-26-22	Removed Zelnorm as a fail first medication, as it has been removed from the US market 6-30-22. 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."
Effective Date (most recent revisions):	11-1-22

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

UM PROGRAM CRITERIA REVISED			
Ibsrela (tenapanor)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy
Ibsrela	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. Summitted clinical documentation must be from an encounter after the start date of the current approval."		

Prior Authorization Approval Criteria

Ibsrela (tenapanor)

Generic name: tenapanor
Brand name: Ibsrela
Medispan GPI: 5255858010**** MONY
Medication class: Sodium/hydrogen exchanger 3 (NHE3) inhibitor
FDA-approved uses: Irritable bowel syndrome with constipation (IBS-C)

Usual dose range:
Indication IBS-C 50mg twice daily

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

Estimated Cost: $21,900 per patient per year

Criteria for use for IBS-C

- 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
- 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)

  -AND-
- Patient has failure, contraindication, or intolerance to Linzess.
  -AND-
- Patient has failure with Amitiza (female patients only) or Trulance.
- Patient is not concomitantly taking Linzess, 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%.
- Patient is tolerating and responding to medication and there continues to be a medical need for the medication.

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- Mechanical GI obstruction (known or suspected).
- Patients less than 6 years of age.

Not approved if:

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

Special Considerations:

- May cause diarrhea; discontinue and rehydrate if severe diarrhea occurs.
- May increase the risk for adverse reactions, including diarrhea and hyperkalemia (requiring hospitalization) in patients with renal impairment, studies have not been completed.
- Tenapanor is contraindicated in patients <6 years of age. The use of tenapanor in patients between 6 to 18 years of age is not recommended. In nonclinical studies in young juvenile rats (approximate human age equivalent of <2 years of age), administration of tenapanor caused decreased body weight and deaths presumed to be due to dehydration.

References:

2. Ibsrela (tenapanor) [product monograph]. Montreal, Quebec, Canada: Knight Therapeutics Inc; April 2020.
3. Chey WD, Lembo AJ, Rosenbaum DP. Efficacy of tenapanor in treating patients with irritable bowel syndrome with constipation: a 12-week, placebo-controlled phase 3 trial (T3MPO-1). Am J Gastroenterol. 2020;115(2):281-293. doi:10.14309/ajg.0000000000000516[PubMed 31934897]

MedOne P&T Committee approval: Date: 4-7-22

Initial adoption:	4-7-22
Revised:	8-26-22
8-26-22	Removed Zelnorm as a fail first medication, as it has been removed from the US market 6-30-22. 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. Summitted clinical documentation must be from an encounter after the start date of the current approval."
Effective Date (most recent revisions):	11-1-22

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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."		

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:

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:

4. 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	Changed initial and ongoing duration Reduced try/fail criteria from 4 to 3
8-26-22	Removed Zelnorm as a fail first medication, as it has been removed from the US market 6-30-22. 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."
Effective Date (most recent revisions):	11-1-22

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UM PROGRAM CRITERIA REVISED			
Mavyret (glecaprevir-pibrentasvir)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy
Mavyret	3. Expanded dosing information. 4. Updated AWP – 8/31/22. 5. Indications updated to reflect current FDA guidelines. 6. Updated the age from 12 to 3 years. 7. Updated Metavir requirement to F2-F4. 8. Added the substance abuse qualification in criteria. 9. Further defined therapy adherence requirement.		

Prior Authorization Approval Criteria

Mavyret (glecaprevir-pibrentasvir)

Generic name:	glecaprevir-pibrentasvir
Brand name:	Mavyret
Medispan GPI:	12359902350320 MON
Medication class:	Antiviral
FDA-approved uses:	**Adult and pediatric patients 3 years and older with chronic HCV genotype (GT) 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A).** **Adult and pediatric patients 3 years and older with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both.**

Usual dose range:

Treatment Naïve Adult Patients – Genotype 1, 2, 3, 4, 5, 6 – No cirrhosis	Dosing: 1 tablet (300mg-120mg) daily for 8 weeks
Treatment Naïve Adult Patients – Genotype 1, 2,	Dosing: 1 tablet (300mg-120mg) daily for 8 weeks

3, 4, 5, 6 – Compensated cirrhosis (Child-Pugh A)	
Treatment NS5A Experienced Adult Patients – Genotype 1 – No cirrhosis	Dosing: 1 tablet (300mg-120mg) daily for 16 weeks
Treatment NS5A Experienced Adult Patients – Compensated cirrhosis (Child-Pugh A)	Dosing: 1 tablet (300mg-120mg) daily for 16 weeks
Treatment NS3/4A PI Experienced Adult Patients – Genotype 1 – No cirrhosis	Dosing: 1 tablet (300mg-120mg) daily for 12 weeks
Treatment NS3/4A PI Experienced Adult Patients – Compensated cirrhosis (Child-Pugh A)	Dosing: 1 tablet (300mg-120mg) daily for 12 weeks
Treatment PRS Experienced Adult Patients – Genotype 1, 2, 4, 5, 6 – No cirrhosis	Dosing: 1 tablet (300mg-120mg) daily for 8 weeks
Treatment PRS Experienced Adult Patients – Genotype 1, 2, 4, 5, 6 – Compensated cirrhosis (Child-Pugh A)	Dosing: 1 tablet (300mg-120mg) daily for 12 weeks
Treatment PRS Experienced Adult Patients – Genotype 3 – No cirrhosis	Dosing: 1 tablet (300mg-120mg) daily for 16 weeks
Treatment PRS Experienced Adult Patients – Genotype 3 – Compensated cirrhosis (Child-Pugh A)	Dosing: 1 tablet (300mg-120mg) daily for 16 weeks
Pediatric patients 3 years or older; weighing less than 20kg	Dosing: Three 50 mg/20 mg packets of oral pellets once daily (150 mg/60 mg per day)
Pediatric patients 3 years or older; weighing 20kg to less than 30kg	Dosing: Four 50 mg/20 mg packets of oral pellets once daily (200 mg/80 mg per day)
Pediatric patients 3 years or older; weighing 30kg to less than 45kg	Dosing: Five 50 mg/20 mg packets of oral pellets once daily (250 mg/100 mg per day)
Pediatric patients 12 years of age or older, or weighting at least 45 pounds	Dosing: Three 100 mg/40 mg tablets once daily (300 mg/120 mg per day)

Duration of Authorization:

Initial:	**8-16 weeks depending on diagnosis**
Ongoing:	**n/a**

Estimated Cost: $15,840 for 84 tablets AWP

Criteria for use for the treatment of chronic hepatitis C genotype 1, 2, 3, 4, 5 or 6 infection in treatment naïve patients without cirrhosis or have compensated cirrhosis:

- 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 chronic hepatitis C genotype 1, 2, 3, 4, 5 or 6 infection
- Must be prescribed by, or in consultation with a Board Certified gastroenterologist, hepatologist, infectious disease, or transplant specialist.
- Documentation includes stage of liver disease, and indicates either significant fibrosis (Metavir F2), advanced fibrosis (Metavir F3), or compensated cirrhosis (Metavir F4).
- Patient must be treatment naïve.
- Will not be used in combination with another HCV direct acting antiviral agent [e.g., Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Sovaldi (sofosbuvir), Zepatier (elbasvir/grazoprevir)]
- Patient fill history documents the ability to adhere to the treatment regimen.
    - -OR- Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen.
- No evidence of abuse of other controlled substance, alcohol, or illicit drugs. Patients with a history of substance abuse must meet the following additional criteria:
    - Substance abuse must be in remission by demonstrating abstinence for the prior 3 months AND a recent negative drug urine screen
    - Must be enrolled and participating in a substance abuse treatment program
- Authorization will be for 8 weeks.

Criteria for use for the treatment of chronic hepatitis C genotype 1, 2, 4, 5 or 6 infection in patients who are treatment-experienced with regimens containing interferon, pegylated interferon, ribavirin, and/or Sovaldi (sofosbuvir) without cirrhosis:

- 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 chronic hepatitis C genotype 1, 2, 4, 5 or 6 infection
- Must be prescribed by, or in consultation with a Board Certified gastroenterologist, hepatologist, infectious disease, or transplant specialist.
- Documentation includes stage of liver disease, and indicates either significant fibrosis (Metavir F2), advanced fibrosis (Metavir F3), or compensated cirrhosis (Metavir F4).
- Patient must have prior treatment experience with a regimen including at least one of the following:
    - Interferon (e.g., Intron-A)
    - Pegylated interferon (e.g., Pegasys, PegIntron)
    - Ribavirin (e.g., Copegus, Rebetol)

    - Sofosbuvir (e.g., Sovaldi)
- Patient must not have treatment experience with any of the following regimens:
    - HCV NS3/4A protease inhibitor [e.g., Incivek (teleprevir), Victrelis (boceprevir), Viekira (dasabuvir/ombitasvir/paritaprevir/ritonavir), Zepatier (elbasvir/grazoprevir)]
    - HCV NS5A inhibitor [e.g., Daklinza (daclatasvir), Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Viekira (dasabuvir/ombitasvir/ paritaprevir/ritonavir), Zepatier (elbasvir/grazoprevir)]
- Patient is without cirrhosis
- Will not be used in combination with another HCV direct acting antiviral agent [e.g., Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Sovaldi (sofosbuvir), Zepatier (elbasvir/grazoprevir)]
- Patient fill history documents the ability to adhere to the treatment regimen
    - OR- Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen.
- No evidence of abuse of other controlled substance, alcohol, or illicit drugs. Patients with a history of substance abuse must meet the following additional criteria:
    - Substance abuse must be in remission by demonstrating abstinence for the prior 12 months AND a recent negative drug urine screen
    - Must be enrolled and participating in a substance abuse treatment program
- Authorization will be for 8 weeks

Criteria for use for the treatment of chronic hepatitis C genotype 1, 2, 4, 5 or 6 infection in patients who are treatment-experienced with regimens containing interferon, pegylated interferon, ribavirin, and/or Sovaldi (sofosbuvir) with cirrhosis:

- 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 chronic hepatitis C genotype 1, 2, 4, 5 or 6 infection
- Must be prescribed by, or in consultation with a Board Certified gastroenterologist, hepatologist, infectious disease, or transplant specialist.
- Patient must have prior treatment experience with a regimen including at least one of the following:
    - Interferon (e.g., Intron-A)
    - Pegylated interferon (e.g., Pegasys, PegIntron)
    - Ribavirin (e.g., Copegus, Rebetol)
    - Sofosbuvir (e.g., Sovaldi)
- Patient must not have treatment experience with any of the following regimens:
    - HCV NS3/4A protease inhibitor [e.g., Incivek (teleprevir), Victrelis (boceprevir), Viekira (dasabuvir/ombitasvir/paritaprevir/ritonavir), Zepatier (elbasvir/grazoprevir)]
    - HCV NS5A inhibitor [e.g., Daklinza (daclatasvir), Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Viekira (dasabuvir/ombitasvir/ paritaprevir/ritonavir), Zepatier (elbasvir/grazoprevir)]
- Patient has compensated cirrhosis (Child-Pugh A).
- Will not be used in combination with another HCV direct acting antiviral agent [e.g., Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Sovaldi (sofosbuvir), Zepatier (elbasvir/grazoprevir)]
- Patient fill history documents the ability to adhere to the treatment regimen
    - OR- Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen.
- No evidence of abuse of other controlled substance, alcohol, or illicit drugs. Patients with a history of substance abuse must meet the following additional criteria:

    - Substance abuse must be in remission by demonstrating abstinence for the prior 12 months AND a recent negative drug urine screen
    - Must be enrolled and participating in a substance abuse treatment program
- Authorization will be for 12 weeks

Criteria for use for the treatment of chronic hepatitis C genotype 3 infection in patients who are treatment-experienced with regimens containing interferon, pegylated interferon, ribavirin, and/or Sovaldi (sofosbuvir) without cirrhosis or have compensated cirrhosis:

- 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 chronic hepatitis C genotype 3 infection
- Must be prescribed by, or in consultation with a Board Certified gastroenterologist, hepatologist, infectious disease, or transplant specialist.
- Documentation includes stage of liver disease, and indicates either significant fibrosis (Metavir F2), advanced fibrosis (Metavir F3), or compensated cirrhosis (Metavir F4).
- Patient must have prior treatment experience with a regimen including at least one of the following:
    - Interferon (e.g., Intron-A)
    - Pegylated interferon (e.g., Pegasys, PegIntron)
    - Ribavirin (e.g., Copegus, Rebetol)
    - Sofosbuvir (e.g., Sovaldi)
- Patient must not have treatment experience with any of the following regimens:
    - HCV NS3/4A protease inhibitor [e.g., Incivek (teleprevir), Victrelis (boceprevir), Viekira (dasabuvir/ombitasvir/paritaprevir/ritonavir), Zepatier (elbasvir/grazoprevir)]
    - HCV NS5A inhibitor [e.g., Daklinza (daclatasvir), Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Viekira (dasabuvir/ombitasvir/ paritaprevir/ritonavir), Zepatier (elbasvir/grazoprevir)]
- Patient is without cirrhosis, or has compensated cirrhosis (Child-Pugh A)
- Will not be used in combination with another HCV direct acting antiviral agent [e.g., Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Sovaldi (sofosbuvir), Zepatier (elbasvir/grazoprevir)]
- Patient fill history documents the ability to adhere to the treatment regimen
    - OR- Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen.
- No evidence of abuse of other controlled substance, alcohol, or illicit drugs. Patients with a history of substance abuse must meet the following additional criteria:
    - Substance abuse must be in remission by demonstrating abstinence for the prior 12 months AND a recent negative drug urine screen
    - Must be enrolled and participating in a substance abuse treatment program
- Authorization will be for 16 weeks

Criteria for use for the treatment of chronic hepatitis C genotype 1 infection in patients who are treatment experienced with an NS5A inhibitor without prior treatment with an NS3/4A protease inhibitor, who are without cirrhosis or have compensated cirrhosis:

- 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 chronic hepatitis C genotype 1 infection
- Must be prescribed by, or in consultation with a Board Certified gastroenterologist, hepatologist, infectious disease, or transplant specialist.
- Documentation includes stage of liver disease, and indicates either significant fibrosis (Metavir F2), advanced fibrosis (Metavir F3), or compensated cirrhosis (Metavir F4).
- Patient must have prior treatment experience with an HCV NS5A inhibitor
    - Daklinza (daclatasvir)
    - Epclusa (sofosbuvir/velpatasvir)
    - Harvoni (ledipasvir/sofosbuvir)
- Patient has no prior treatment experience with an NS3/4A protease inhibitor:
    - Incivek (teleprevir)
    - Olysio (simeprevir)
    - Victrelis (boceprevir)
    - Viekira (dasabuvir/ombitasvir/ paritaprevir/ritonavir)
    - Zepatier (elbasvir/grazoprevir)]
- Patient is without cirrhosis, or has compensated cirrhosis (Child-Pugh A)
- Will not be used in combination with another HCV direct acting antiviral agent [e.g., Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Sovaldi (sofosbuvir), Zepatier (elbasvir/grazoprevir)]
- Patient fill history documents the ability to adhere to the treatment regimen
    - OR- Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen.
- No evidence of abuse of other controlled substance, alcohol, or illicit drugs. Patients with a history of substance abuse must meet the following additional criteria:
    - Substance abuse must be in remission by demonstrating abstinence for the prior 12 months AND a recent negative drug urine screen
    - Must be enrolled and participating in a substance abuse treatment program
- Authorization will be for 16 weeks

Criteria for use for the treatment of chronic hepatitis C genotype 1 infection in patients who are treatment experienced with an NS3/4A protease inhibitor without prior treatment with an NS5A inhibitor, who are without cirrhosis or have compensated cirrhosis

- 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 chronic hepatitis C genotype 1 infection
- Must be prescribed by, or in consultation with a Board Certified gastroenterologist, hepatologist, infectious disease, or transplant specialist.
- Documentation includes stage of liver disease, and indicates either significant fibrosis (Metavir F2), advanced fibrosis (Metavir F3), or compensated cirrhosis (Metavir F4).
- Patient must have prior treatment experience with an NS3/4A protease inhibitor:
    - Incivek (teleprevir)
    - Olysio (simeprevir)
    - Victrelis (boceprevir)
    - Viekira (dasabuvir/ombitasvir/ paritaprevir/ritonavir)
    - Zepatier (elbasvir/grazoprevir)]
- Patient has no prior treatment experience with an HCV NS5A inhibitor
    - Daklinza (daclatasvir)
    - Epclusa (sofosbuvir/velpatasvir)
    - Harvoni (ledipasvir/sofosbuvir)

- Patient is without cirrhosis, or has compensated cirrhosis (Child-Pugh A)
- Will not be used in combination with another HCV direct acting antiviral agent [e.g., Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Sovaldi (sofosbuvir), Zepatier (elbasvir/grazoprevir)]
- Patient fill history documents the ability to adhere to the treatment regimen
    - OR- Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen.
- No evidence of abuse of other controlled substance, alcohol, or illicit drugs. Patients with a history of substance abuse must meet the following additional criteria:
    - Substance abuse must be in remission by demonstrating abstinence for the prior 12 months AND a recent negative drug urine screen
    - Must be enrolled and participating in a substance abuse treatment program
- Authorization will be for 12 weeks

Criteria for use for the treatment of hepatitis C genotype 1, 2, 3, 4, 5 or 6 infection in kidney or liver transplant recipients who are without cirrhosis or have compensated cirrhosis

- 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 chronic hepatitis C genotype 1, 2, 3, 4, 5, 6 infection
- Must be prescribed by, or in consultation with a Board Certified gastroenterologist, hepatologist, infectious disease, or transplant specialist.
- Documentation includes stage of liver disease, and indicates either significant fibrosis (Metavir F2), advanced fibrosis (Metavir F3), or compensated cirrhosis (Metavir F4).
- Patient has received a kidney or liver transplant
- Patient is without cirrhosis, or has compensated cirrhosis (Child-Pugh A)
- Will not be used in combination with another HCV direct acting antiviral agent [e.g., Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Sovaldi (sofosbuvir), Zepatier (elbasvir/grazoprevir)]
- Patient fill history documents the ability to adhere to the treatment regimen
    - OR- Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen.
- No evidence of abuse of other controlled substance, alcohol, or illicit drugs. Patients with a history of substance abuse must meet the following additional criteria:
    - Substance abuse must be in remission by demonstrating abstinence for the prior 3 months AND a recent negative drug urine screen
    - Must be enrolled and participating in a substance abuse treatment program
- Authorization will be for 12 weeks

Criteria continuation of therapy

- n/a

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- Moderate or severe hepatic impairment (Child-Pugh B or C) or those with any history of prior hepatic decompensation.
- Concomitant use with atazanavir or rifampin

Not approved if:

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

Special Considerations:

- Hepatic decompensation/failure, including fatal outcomes, have been reported; the majority of severe outcomes occurred in patients with advanced liver disease with moderate or severe hepatic impairment prior to therapy initiation (Child-Pugh B or C; use of glecaprevir/pibrentasvir is contraindicated in this population); some occurred in those with mild liver impairment (Child-Pugh A) at baseline with a prior decompensation event (ie, prior history of ascites, variceal bleeding, encephalopathy)
- Rare cases of hepatic decompensation/failure were reported in patients without cirrhosis or with compensated cirrhosis (Child-Pugh A), in patients taking a concomitant medication not recommended for coadministration, or in patients with confounding factors (eg, serious liver-related medical or surgical comorbidities); monitoring recommended and discontinuation may be necessary
- Rapid reduction in hepatitis C viral load during direct-acting antiviral (DAA) therapy for hepatitis C may lead to improvement in glucose metabolism in patients with diabetes, potentially resulting in symptomatic hypoglycemia if antidiabetic agents are continued at the same dose. Monitor for changes in glucose tolerance and inform patients of the risk of hypoglycemia during DAA therapy, particularly within the first 3 months. Modification of antidiabetic may be necessary.
- Hepatitis B virus (HBV) reactivation has been reported in hepatitis C virus (HCV)/HBV coinfected patients who were receiving or had completed treatment with HCV direct-acting antivirals and were not receiving HBV antiviral therapy; some cases have resulted in fulminant hepatitis, hepatic failure, and death. Test all patients for evidence of current or prior HBV infection prior to initiation of treatment; monitor HCV/HBV co-infected patients for hepatitis flare or HBV reactivation during treatment and post-treatment follow-up. Initiate treatment for HBV infection as clinically indicated.

References:

5. Mavyret (glecaprevir/pibrentasvir) [prescribing information]. North Chicago, IL: AbbVie Inc; September 2021
6. American Association for the Study of Liver Diseases (AASLD), Infectious Diseases Society of America (IDSA). HCV guidance: recommendations for testing, managing, and treating hepatitis C. https://www.hcvguidelines.org/. Updated October 5, 2021.
7. Ciancio A, Bosio R, Bo S, et al. Significant improvement of glycemic control in diabetic patients with HCV infection responding to direct-acting antiviral agents. J Med Virol. 2018;90(2):320-327. doi:10.1002/jmv.24954[PubMed 28960353]
8. Hum J, Jou JH, Green PK, et al. Improvement in Glycemic Control of Type 2 Diabetes After Successful Treatment of Hepatitis C Virus. Diabetes Care. 2017;40(9):1173-1180. doi:10.2337/dc17-0485[PubMed 28659309]

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

Initial adoption: 1-1-17
Revised: 8-30-22

8-30-22

1. Expanded dosing information.
2. Updated AWP – 8/31/22.
3. Indications updated to reflect current FDA guidelines.
4. Updated the age from 12 to 3 years.
5. Updated Metavir requirement to F2-F4.
6. Added the substance abuse qualification in criteria.
7. Further defined therapy adherence requirement.

Effective Date (most recent revisions): 11-1-22

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

UM PROGRAM CRITERIA REVISED			
Motegrity (prucalopride)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy
Motegrity	1. 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."		

Prior Authorization Approval Criteria

Motegrity (prucalopride)

Generic name: prucalopride
Brand name: Motegrity
Medication class: Serotonin 5-HT4 Receptor Agonist
FDA-approved uses: Chronic idiopathic constipation (CIC)

Usual dose range:
CIC 2mg daily

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

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 has failure, contraindication, or intolerance to Linzess.
- Patient is not concomitantly taking Linzess, 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.
- Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, obstructive ileus, severe inflammatory conditions of the GI tract (eg, Crohn disease, ulcerative colitis, toxic megacolon/megarectum).

Not approved if:

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

Special Considerations:

- Renal impairment:
  - CrCl < 30 mL/min: 1 mg once daily
  - ESRD: avoid use
- Monitor for worsening depression, or emerging suicidal ideation

References:

9. Motegrity (prucalopride) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America; November 2020.

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

Adopted:	1-1-17
Revised:	8-27-21 12-7-21 8-26-22
8-27-21	Changed initial and ongoing duration Reduced try/fail criteria from 4 to 3 Added Linzess/Movantik trials
12-7-21	Corrected approval duration from indefinite to initial approvals are 3 months and renewal approvals are 12 months
8-26-22	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."
Effective Date (most recent revisions):	11-1-22

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

UM PROGRAM CRITERIA REVISED		
Movantik (naloxegol)		
Program Type:	☒ Prior Authorization ☒ Quantity Limit	☒ Step Therapy
Movantik	1. 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."	

Prior Authorization Approval Criteria

Movantik (naloxegol)

Generic name: naloxegol
Brand name: Movantik
Medication class: Opioid antagonist
FDA-approved uses: Opioid-induced constipation (OIC)

Usual dose range:
OIC 25 mg once daily; if not tolerated, reduce to 12.5 mg once daily

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

Criteria for use for opioid induced 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.
- Patient has OIC and chronic non-cancer pain
- Patient has chronic use of an opioid agent in the past 30 days
- 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)
- Will not be used concomitantly with other opioid antagonists.
- Patient is not concomitantly taking Amitiza or Symproic.

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.
- GI obstruction (known or suspected) or at risk of recurrent obstruction;
- Concomitant use with strong CYP3A4 inhibitors (eg, clarithromycin, ketoconazole)

Not approved if:

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

Special Considerations:

- Renal impairment:

- CrCl < 60 mL/min: 12.5 mg once daily; increase to 25 mg once daily if tolerated and monitor for adverse reactions.
- Discontinue maintenance laxative therapy before starting Movantik; may resume laxatives if patients have OIC symptoms after taking Movantik for 3 days.
- Alteration in analgesic dosing regimen prior to starting Movantik is not required.
- Avoid consumption of grapefruit
- Must be dispensed with approved medication guide

References:

10. Movantik (naloxegol) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; April 2020.

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

Adopted:	1-1-17
Revised:	8-27-21 8-26-22
8-27-21	Changed initial and ongoing duration Reduced try/fail criteria from 4 to 3
8-26-22	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."
Effective Date (most recent revisions):	11-1-22

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

UM PROGRAM CRITERIA REVISED			
Symproic (naldemedine)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy
Symproic	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."		

Prior Authorization Approval Criteria

Symproic (naldemedine)

Generic name:	naldemedine
Brand name:	Symproic
Medication class:	Opioid antagonist
FDA-approved uses:	Opioid-induced constipation (OIC)
Usual dose range:	
OIC	0.2mg once daily

Duration of Authorization:

Initial:	3 months
Ongoing:	12 months

Criteria for use for opioid induced 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.
- Patient has OIC and chronic non-cancer pain.
- Patient has chronic use of an opioid agent in the past 30 days.
- 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 has failure, contraindication, or intolerance to Movantik.
- Will not be used concomitantly with other opioid antagonists.
- Patient is not concomitantly taking Movantik or Amitiza.

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.
- GI obstruction (known or suspected) or at risk of recurrent obstruction.
- Concomitant use with strong CYP3A4 inhibitors (eg, clarithromycin, ketoconazole).
- Avoid use in severe impairment (Child-Pugh Class C).

Not approved if:

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

Special Considerations:

- Alteration in analgesic dosing regimen prior to starting Symproic is not required.

References:

11. Symproic (naldemedine) [prescribing information]. Raleigh, NC: BioDelivery Sciences International, Inc; May 2020.

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

Adopted:	1-1-17
Revised:	8-27-21
	8-26-22
8-27-21	Changed initial and ongoing duration
	Reduced try/fail criteria from 4 to 3
	Added Movantik trials

8-26-22	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."
Effective Date (most recent revisions):	11-1-22

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

UM PROGRAM CRITERIA REVISED			
Trulance (plecanatide)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy
Trulance	3. 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."		

Prior Authorization Approval Criteria

Trulance (plecanatide)

Generic name:	plecanatide
Brand name:	Trulance
Medication class:	Guanylate Cyclase-C Agonist
FDA-approved uses:	Chronic idiopathic constipation (CIC) Irritable bowel syndrome with constipation (IBS-C)

Usual dose range:

CIC	3mg daily
IBS	3mg daily

Duration of Authorization:

Initial:	3 months
Ongoing:	12 months

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 has failure, contraindication, or intolerance to Linzess.
- Patient is not concomitantly taking Linzess, Motegrity, or Amitiza.

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.
- Patient was born female.
- 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 has failure, contraindication, or intolerance to Linzess.
- Patient is not concomitantly taking Linzess or Amitiza.

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.
- Mechanical GI obstruction (known or suspected).
- Pediatric patients younger than 6 years.

Not approved if:

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

Special Considerations:

- No dosage adjustments in renal or hepatic function impairment, dosage adjustment unlikely due to low systemic absorption.

References:

12. Trulance (plecanatide) [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals, a division of Bausch Health US, LLC; February 2021.

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

Adopted:	1-1-17
Revised:	8-27-21 8-26-22
8-27-21	Changed initial and ongoing duration Reduced try/fail criteria from 4 to 3 Added Linzess trials
8-26-22	Removed Zelnorm as a fail first medication, as it has been removed from the US market 6-30-22. 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."
Effective Date (most recent revisions):	11-1-22

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

UM PROGRAM CRITERIA REVISED			
Vraylar (cariprazine)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy
Vraylar	4. 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."		

Prior Authorization Approval Criteria

Vraylar (cariprazine)

Generic name:	Vraylar	
Brand name:	cariprazine	
Medispan GPI:	5940001810****	MONY
Medication class:	Second generation (atypical) antipsychotic	
FDA-approved uses:	**Bipolar I disorder in adults** **Schizophrenia in adults**	
Usual dose range:		
Bipolar Mania	Initial: 1.5mg per day	Maximum Adult: 6mg/day
Bipolar Depression	Initial: 1.5mg per day	Maximum Adult: 3mg/day
Schizophrenia	Initial: 1.5mg per day	Maximum Adult: 6mg/day
Duration of Authorization:		
Initial:	3 months	
Ongoing:	12 months	

Estimated Cost:

Criteria for use for Bipolar I Disorder

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be 18 years or older
- Must be prescribed by, or in consultation with a psychiatrist or mental health professional.
- Patient has failure, contraindication, or intolerance to 2 preferred generic antipsychotics:
    - Aripiprazole (Abilify)
    - Chlorpromazine (Thorazine)
    - Clozapine (Clozaril)
    - Fluphenazine (Prolixin)
    - Haloperidol (Haldol)
    - Loxapine (Loxitane)
    - Olanzapine (Zyprexa)
    - Paliperidone (Invega)
    - Pimozide (Orap)
    - Quetiapine IR/ER (Seroquel)
    - Risperidone (Risperdal)
    - Thiothixene (Navane)
    - Trifluoperzine (Stelazine)
    - Ziprasidone (Geodon)

Criteria for use for Schizophrenia

- Must be 18 years or older
- Must be prescribed by, or in consultation with a psychiatrist or mental health professional.
- Patient has failure, contraindication, or intolerance to 2 preferred generic antipsychotics:
    - Aripiprazole (Abilify)
    - Chlorpromazine (Thorazine)
    - Clozapine (Clozaril)
    - Fluphenazine (Prolixin)
    - Haloperidol (Haldol)
    - Loxapine (Loxitane)
    - Olanzapine (Zyprexa)
    - Paliperidone (Invega)
    - Pimozide (Orap)
    - Quetiapine IR/ER (Seroquel)
    - Risperidone (Risperdal)
    - Thiothixene (Navane)
    - Trifluoperzine (Stelazine)
    - Ziprasidone (Geodon)

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.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- Dosages above 6mg; as they do not confer significant benefit but increase the risk of dose-related adverse reactions
- In patients with impaired renal function (CrCl < 30mL/min), use is not recommended (has not been studied).
- In patients with severely impaired hepatic function (Child-Pugh class C), use is not recommended (has not been studied).

Special Considerations:

- May be taken with or without food.
- Vraylar is not indicated for the treatment of major depressive disorder. Data from a randomized, double-blind, placebo-controlled trial in patients with an inadequate response to antidepressants supports the use of cariprazine as an antidepressant augmentation strategy in unipolar major depressive disorder. (Durgam 2016); however Major Depressive Disorder is still considered off label.
- Antidepressants increased the risk of suicidal thoughts and behavior in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors.
- Use may be associated with neuroleptic malignant syndrome (NMS); monitor for mental status changes, fever, muscle rigidity, and/or autonomic instability (risk may be increased in patients with Parkinson disease or Lewy body dementia).
- May cause extrapyramidal symptoms (EPS), including pseudoparkinsonism, acute dystonic reactions, akathisia, and tardive dyskinesia (potentially irreversible). Risk of these reactions is generally much lower relative to typical/conventional antipsychotics; frequencies reported are similar to placebo. Risk of dystonia (and probably other EPS) may be greater with increased doses, use of conventional antipsychotics, males, and younger patients. Factors associated with greater vulnerability to tardive dyskinesia include older age, female gender combined with postmenopausal status, Parkinson disease, pseudoparkinsonism symptoms, affective disorders (particularly major depressive disorder), concurrent medical diseases such as diabetes, previous brain damage, alcoholism, poor treatment response, and high doses of antipsychotics.
- May increase the risk for falls due to somnolence, orthostatic hypotension, and motor or sensory instability.
- Atypical antipsychotics have been associated with development of hyperglycemia; in some cases, may be extreme and associated with ketoacidosis, hyperosmolar coma, or death. Incidence varies with product; compared to other antipsychotics, the risk of metabolic side effects like hyperglycemia with lurasidone is minimal to low.
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References:

13. Vraylar (cariprazine) [prescribing information]. Irvine, CA: Allergan USA Inc; May 2019.

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

Adopted:	1-1-17
Revised:	9-10-21
	12-7-21
	8-22-22
9-10-21	1. Moved from non-preferred brand to preferred brand (Cat C to Cat B) 2. Added mental health professional requirement 3. Updated initial auth from 3 months to 12 months
12-7-21	Clarification for Update on 9-17-21 – Authorization period was updated to initial approval for 3 months, and renewal approval for 12 months; previously indefinite

8-22-22	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. Summitted clinical documentation must be from an encounter after the start date of the current approval.”
Effective Date (most recent revisions):	11-1-22

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