Up to half of long-term care residents suffer from constipation\(^1\-^4\)

**Could they be suffering from Irritable Bowel Syndrome with Constipation (IBS-C) or Chronic Idiopathic Constipation (CIC)?\(^5\-^7\)**

**#1 Identifying IBS-C and CIC**

- When constipation is more than occasional, it may be CIC or IBS-C\(^7\)
- The symptoms of CIC include hard stools, constipation, and infrequent and incomplete bowel movements.\(^5\) The symptoms of IBS-C include abdominal pain, constipation, and incomplete bowel movements\(^4\)
- They are both chronic conditions, which can cause your residents to suffer from recurring symptoms\(^7\)

**#2 What is LINZESS?**

LINZESS\textsuperscript{\textregistered} (linaclotide) is a once-daily capsule that’s approved to help adults manage symptoms of IBS-C and CIC.\(^9\)
- It’s the first and only guanylate cyclase-C (GC-C) agonist to be approved in its class\(^10\)

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- It’s the first and only guanylate cyclase-C (GC-C) agonist to be approved in its class\(^10\)

**IMPORTANT SAFETY INFORMATION**

**Adverse Reactions**

- In IBS-C clinical trials, the most common adverse reactions in LINZESS-treated patients (incidence 22% and greater than placebo) were diarrhea (20% vs 3% placebo), abdominal pain (7% vs 5%), flatulence (4% vs 2%), headache (4% vs 3%), viral gastroenteritis (3% vs 1%) and abdominal distension (2% vs 1%).
- In CIC clinical trials, the most common adverse reactions in LINZESS-treated patients (incidence 22% and greater than placebo) were diarrhea (16% vs 5% placebo), abdominal pain (7% vs 6%), flatulence (6% vs 5%), upper respiratory tract infection (5% vs 4%), sinusitis (3% vs 2%) and abdominal distension (3% vs 2%).

Please see additional Important Safety Information throughout and enclosed full Prescribing Information.

**Diarrhea**

- The incidence of diarrhea was similar in the IBS-C and CIC populations.
- Patients should be instructed to stop LINZESS if severe diarrhea occurs and to contact their healthcare provider.
- Use of LINZESS should be avoided in pediatric patients 6 through 17 years of age. Although there were no deaths in pediatric patients under 18 years of age, there were deaths in pediatric patients 6 through 17 years of age. The safety and effectiveness of LINZESS has not been established in pediatric patients under 18 years of age.

**Patient and Family Education**

- Inform residents about the symptoms of IBS-C and CIC.
- Inform residents about the importance of taking LINZESS on a daily basis.
- Inform residents about the importance of consuming adequate fluid during treatment.
- Inform residents about the importance of following a healthy diet and lifestyle.

**Medication Storage**

- LINZESS should be stored at room temperature between 68°F and 77°F. LINZESS needs to be protected from moisture, heat, and freezing.

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#6 How to administer LINZESS

For IBS-C, the recommended dose is 290 mcg taken orally once daily.\(^9\)

For CIC, the recommended dose is 145 mcg taken orally once daily.\(^9\)

Residents should take one capsule a day, every day.

#7 Storing LINZESS

LINZESS should be stored at room temperature between 68°F and 77°F. LINZESS needs to be protected from moisture, heat, and freezing.

#8 What is LINZESS?

LINZESS\textsuperscript{\textregistered} (linaclotide) is indicated in adults for the treatment of both Irritable Bowel Syndrome with Constipation (IBS-C) and Chronic Idiopathic Constipation (CIC).

**IMPORTANT SAFETY INFORMATION**

**WARNING: PEDIATRIC RISK**

LINZESS is contraindicated in pediatric patients under 6 years of age. In nonclinical studies, administration of a single, clinically relevant adult oral dose of linaclotide caused deaths due to dehydration in young juvenile mice. Use of LINZESS should be avoided in pediatric patients 6 through 17 years of age. The safety and efficacy of LINZESS has not been established in pediatric patients under 18 years of age.

**Please see additional Important Safety Information throughout and enclosed full Prescribing Information.**
The clinical relevance of the effect on pain fibers has not been established.

LINZESS has formulary status on 76% of Medicare Part D plans.12

LINZESS is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

LINZESS is contraindicated in pediatric patients under 6 years of age.

LINZESS may be appropriate for a wide variety of your residents with IBS-C or CIC. Patients with varying degrees of symptom severity were included in the clinical trials.8

LINZESS is the #1 prescribed branded treatment for IBS-C and CIC.11

#5 Who is LINZESS appropriate for?

Many people with IBS-C or CIC find their condition embarrassing to talk about, so additional prompting may be necessary. Listen to how residents describe their symptoms. IBS-C symptoms include belly pain, constipation, and infrequent and incomplete bowel movements. CIC symptoms include hard stools, constipation, and infrequent bowel movements. LINZESS may be appropriate for a wide variety of your residents with IBS-C or CIC. Patients with varying degrees of symptom severity were included in the clinical trials.8

Clinical studies of LINZESS did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.8

IMPORTANT SAFETY INFORMATION (cont.)

Contraindications

• LINZESS is contraindicated in pediatric patients under 6 years of age.

• LINZESS is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

#4 How does LINZESS work?

LINZESS works differently from laxatives. It is thought to work in two ways based on nonclinical studies:* LINZESS acts locally in the intestines to increase cyclic guanosine monophosphate (cGMP), which is thought to decrease pain-sensing nerve activity. It also increases fluid secretion to accelerate transit.3

*The clinical relevance of the effect on pain fibers has not been established.

#3 Why LINZESS?

• LINZESS may provide effective relief of the recurring abdominal pain and constipation associated with IBS-C and the chronic constipation symptoms associated with CIC.9

• Taken once daily, LINZESS can help proactively manage symptoms and help your residents have more frequent and complete bowel movements that are easier to pass.3

• LINZESS acts locally in the intestines. LINZESS is minimally absorbed with low systemic availability. While no drug-drug interaction studies have been conducted, no systemic drug-drug interactions are anticipated.9

• Treating chronic symptoms with remedies meant for occasional symptoms can leave your residents frustrated. IBS-C and CIC may require a different treatment than the OTC laxatives you are currently using.3

• LINZESS is the #1 prescribed branded treatment for IBS-C and CIC.11

• LINZESS has preferred formulary status on 76% of Medicare Part D plans.12

#6 How to administer LINZESS

• For IBS-C, the recommended dose is 290 mcg taken orally once daily.5

• For CIC, the recommended dose is 145 mcg taken orally once daily.6

• Residues should take one capsule a day, every day. LINZESS should be taken on an empty stomach, at least 30 minutes before the first meal of the day.2

• Capsules should be swallowed whole. They should not be broken or chewed.2

#7 Storing LINZESS

• The desiccant should not be removed from the container, and bottles should be kept tightly closed in a dry place.4

• LINZESS should be stored at room temperature between 68° F and 77° F. LINZESS needs to be protected from moisture, so it should be kept in the original container.4

• LINZESS is often stored in an alternate drawer in facilities/homes because it should not be subdivided or repackaged.9

#8 What are some of the possible side effects of LINZESS?

• Common adverse reactions were reported at least in 2% of LINZESS patients, and at an incidence greater than placebo in the IBS-C and CIC trials.9

• Diarrhea was the most common adverse reaction in LINZESS-treated patients in the double-blind placebo-controlled trials. Severe diarrhea was reported in 2% of LINZESS-treated patients.9

• Less than or equal to 1% of LINZESS-treated patients reported fecal incontinence or dehydration.9

• Other common side effects of LINZESS include gas, stomach-area (abdomen) pain, swelling, or a feeling of fullness or pressure in your abdomen (distension).9

IMPORTANT SAFETY INFORMATION (cont.)

Warnings and Precautions

Pediatric Risk

• LINZESS is contraindicated in pediatric patients under 6 years of age. The safety and effectiveness of LINZESS in pediatric patients under 18 years of age have not been established. In neonatal mice, increased fluid secretion as a consequence of GC-C agonism resulted in mortality within the first 24 hours due to dehydration. Due to increased intestinal expression of GC-C, children under 6 years of age may be more likely than older children and adults to develop significant diarrhea and its potentially serious consequences.

• Use of LINZESS should be avoided in pediatric patients 6 through 17 years of age. Although there were no deaths in older juvenile mice, given the deaths in young juvenile mice and the lack of clinical safety and efficacy data in pediatric patients, use of LINZESS should be avoided in pediatric patients 6 through 17 years of age.

Diarrhea

• Diarrhea was the most common adverse reaction in LINZESS-treated patients in the pooled IBS-C and CIC double-blind placebo-controlled trials. Severe diarrhea was reported in 2% of LINZESS-treated patients. The incidence of diarrhea was similar in the IBS-C and CIC populations.

• Patients should be instructed to stop LINZESS if severe diarrhea occurs and to contact their healthcare provider. The healthcare provider should consider dose suspension and rehydration.
The clinical relevance of the effect on pain fibers has not been established.

**LINZESS has formulary status on 76% of Medicare Part D plans.**

**Contraindications**

Listen to how residents describe their symptoms. IBS-C symptoms include belly pain, constipation, and infrequent and incomplete bowel movements. Many people with IBS-C or CIC find their condition embarrassing to talk about, so additional prompting may be necessary.

**Treating chronic symptoms with remedies meant for occasional symptoms can leave your residents frustrated. IBS-C and CIC are both chronic conditions, which can cause your residents to feel neglected and frustrated.**

**LINZESS is the #1 prescribed branded treatment for IBS-C and CIC.**

**#3 Why LINZESS?**

- LINZESS may provide effective relief of the recurring abdominal pain and constipation associated with IBS-C and the chronic constipation symptoms associated with CIC.
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- LINZESS acts locally in the intestines. LINZESS is minimally absorbed with low systemic availability. While no drug-drug interaction studies have been conducted, no systemic drug-drug interactions are anticipated.
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**IMPORTANT SAFETY INFORMATION (cont.)**

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**IMPORTANT SAFETY INFORMATION (cont.)**

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- In CIC clinical trials, the most common adverse reactions in LINZESS-treated patients (incidence ≥2% and greater than placebo) were diarrhea (16% vs 5% placebo), abdominal pain (7% vs 6%), flatulence (6% vs 5%), upper respiratory tract infection (5% vs 4%), sinusitis (3% vs 2%) and abdominal distension (3% vs 2%).

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References: