

Constipation Agents Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
02-23-2026

Date of Origin

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Amitiza	lubiprostone cap	24 MCG ; 8 MCG	M ; N ; O ; Y	O ; Y		
Relistor	methylnaltrexone bromide inj	8 MG/0.4ML	M ; N ; O ; Y	N		
Relistor	methylnaltrexone bromide inj	12 MG/0.6ML	M ; N ; O ; Y	N		
Relistor	methylnaltrexone bromide inj	12 MG/0.6ML	M ; N ; O ; Y	N		
Relistor	methylnaltrexone bromide tab	150 MG	M ; N ; O ; Y	N		
Motegrity	prucalopride succinate tab	1 MG ; 2 MG	M ; N ; O ; Y	O ; Y		
Ibsrela	tenapanor hcl tab	50 MG	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
			30	Syringes	30	DAYS	12 mL= 30 syringes		
Amitiza	Lubiprostone Cap 24 MCG	24 MCG	60	Capsules	30	DAYS			
Amitiza	Lubiprostone Cap 8 MCG	8 MCG	120	Capsules	30	DAYS			
Ibsrela	tenapanor hcl tab	50 MG	60	Tablets	30	DAYS			
Linzess	linaclotide cap	145 MCG ; 290 MCG ; 72 MCG	30	Capsules	30	DAYS			
Motegrity	prucalopride succinate tab	1 MG ; 2 MG	30	Tablets	30	DAYS			
Movantik	naloxegol oxalate tab	12.5 MG ; 25 MG	30	Tablets	30	DAYS			
Relistor	methylnaltrexone bromide inj	8 MG/0.4 ML	30	Syringes	30	DAYS			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Relistor	methylnaltrexone bromide inj	12 MG/0.6 ML	30	Syringes	30	DAYS			
Relistor	Methylnaltrexone Bromide Inj 12 MG/0.6ML (20 MG/ML)	12 MG/0.6 ML	60	Vials	30	DAYS	Quantity Limit allows for dosing for individuals at least 90th percentile weight. CDC 90th percentile weight for adult males 20 years of age and over is 113.3 kg(17).		
Relistor	Methylnaltrexone Bromide Tab 150 MG	150 MG	90	Tablets	30	DAYS			
Symproic	naldemedine tosylate tab	0.2 MG	30	Tablets	30	DAYS			
Trulance	plecanatide tab	3 MG	30	Tablets	30	DAYS			

ADDITIONAL QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
52580050102015				12 mL= 30 syringes			
52580050102020	Relistor	Methylnaltrexone Bromide Inj 12 MG/0.6ML (20 MG/ML)	12 MG/0.6 ML	Quantity Limit allows for dosing for individuals at least 90th percentile weight. CDC 90th percentile weight for adult males 20 years of age and over is 113.3 kg(17).		09-22-2025	

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Amitiza	lubiprostone cap	24 MCG ; 8 MCG	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Ibsrela	tenapanor hcl tab	50 MG	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Motegrity	prucalopride succinate tab	1 MG ; 2 MG	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Relistor	methylnaltrexone bromide inj	8 MG/0.4ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Relistor	methylnaltrexone bromide inj	12 MG/0.6ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Relistor	methylnaltrexone bromide inj	12 MG/0.6ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Relistor	methylnaltrexone bromide tab	150 MG	Basic ; Basic Annual ; Enhanced ; Enhanced Annual

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Amitiza	Lubiprostone Cap 24 MCG	24 MCG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Amitiza	Lubiprostone Cap 8 MCG	8 MCG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Ibsrela	tenapanor hcl tab	50 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Linzess	linaclotide cap	145 MCG ; 290 MCG ; 72 MCG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Motegrity	prucalopride succinate tab	1 MG ; 2 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Movantik	naloxegol oxalate tab	12.5 MG ; 25 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Relistor	methylnaltrexone bromide inj	8 MG/0.4ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Relistor	methylnaltrexone bromide inj	12 MG/0.6ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Relistor	Methylnaltrexone Bromide Inj 12 MG/0.6ML (20 MG/ML)	12 MG/0.6ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ;

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Relistor	Methylnaltrexone Bromide Tab 150 MG	150 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Symproic	naldemedine tosylate tab	0.2 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Trulance	plecanatide tab	3 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			2026 ; Topaz ; Whole Foods

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p>Amitiza (lubiprostone)* Ibsrela (tenapanor) Motegrity (prucalopride)* Relistor (methylnaltrexone)</p> <p>*-generic available</p> <p>Initial Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of irritable bowel syndrome with constipation (IBS-C) AND ALL of the following: <ol style="list-style-type: none"> 1. The patient has had IBS-C symptoms for greater than or equal to 3 months AND 2. ONE of the following: <ol style="list-style-type: none"> A. The requested agent is Ibsrela (tenapanor) OR B. The requested agent is Amitiza (lubiprostone) AND ONE of the following: <ol style="list-style-type: none"> 1. The patient's sex is female OR 2. The requested agent is medically appropriate for the patient's sex and the intended diagnosis AND 3. ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The prescriber has stated that the patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer OR B. The prescriber has submitted documentation that the patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat an associated condition related to stage four advanced metastatic cancer [chart notes are required] AND 2. The use of the requested agent is consistent with best practices for the treatment of stage four advanced, metastatic cancer, or an associated condition; supported by peer-reviewed, evidence-based literature; and approved by the United States Food and Drug Administration OR B. The patient has tried and had an inadequate response to at least 2 standard laxative therapy classes (e.g., bulk forming, stimulant, enema, osmotic, or stool softener) OR C. The patient has an intolerance or hypersensitivity to at least 2 standard laxative therapy classes OR D. The patient has an FDA labeled contraindication to ALL standard laxative therapy classes OR B. The patient has a diagnosis of chronic idiopathic constipation (CIC) AND ALL of the following:

Module	Clinical Criteria for Approval
	<ol style="list-style-type: none"> 1. The patient has had CIC symptoms for greater than or equal to 3 months AND 2. The requested agent is Amitiza (lubiprostone) or Motegrity (prucalopride) AND 3. ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The prescriber has stated that the patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer OR B. The prescriber has submitted documentation that the patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat an associated condition related to stage four advanced metastatic cancer [chart notes are required] AND 2. The use of the requested agent is consistent with best practices for the treatment of stage four advanced, metastatic cancer, or an associated condition; supported by peer-reviewed, evidence-based literature; and approved by the United States Food and Drug Administration OR B. The patient has tried and had an inadequate response to at least 2 standard laxative therapy classes (e.g., bulk forming, stimulant, enema, osmotic, or stool softener) OR C. The patient has an intolerance or hypersensitivity to at least 2 standard laxative therapy classes OR D. The patient has an FDA labeled contraindication to ALL standard laxative therapy classes OR C. The patient has a diagnosis of opioid-induced constipation (OIC) AND ALL of the following: <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The requested agent is Relistor (methylnaltrexone) tablet OR B. The requested agent is Amitiza (lubiprostone), AND the patient is not currently receiving a diphenylheptane opioid (e.g. methadone) AND 2. ONE of the following: <ol style="list-style-type: none"> A. The patient has chronic non-cancer pain OR B. The patient has chronic pain related to prior cancer or its treatment OR C. The patient has active cancer pain OR B. The request is for Relistor (methylnaltrexone) injection, and the patient is receiving palliative care AND ONE of the following: <ol style="list-style-type: none"> 1. The patient has advanced illness OR 2. The patient has pain caused by active cancer AND 2. The patient has chronic use of an opioid agent in the past 30 days AND 3. ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The prescriber has stated that the patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer OR B. The prescriber has submitted documentation that the patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat an associated

Module	Clinical Criteria for Approval				
	<p style="text-align: center;">condition related to stage four advanced metastatic cancer [chart notes are required] AND</p> <ol style="list-style-type: none"> 2. The use of the requested agent is consistent with best practices for the treatment of stage four advanced, metastatic cancer, or an associated condition; supported by peer-reviewed, evidence-based literature; and approved by the United States Food and Drug Administration OR <ol style="list-style-type: none"> B. The patient has tried and had an inadequate response to at least 2 standard laxative therapy classes (e.g., stimulant, enema, osmotic, or stool softener, but not including fiber or bulking agents) OR C. The patient has an intolerance or hypersensitivity to at least 2 standard laxative therapy classes OR D. The patient has an FDA labeled contraindication to ALL standard laxative therapy classes AND <ol style="list-style-type: none"> 2. If the patient has an FDA labeled indication, ONE of the following: <ol style="list-style-type: none"> A. The patient’s age is within FDA labeling for the requested indication for the requested agent OR B. There is support for using the requested agent for the patient’s age for the requested indication AND 3. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following: <table border="1" data-bbox="467 947 1182 1024" style="margin: 10px auto;"> <thead> <tr> <th data-bbox="467 947 824 982">Brand</th> <th data-bbox="824 947 1182 982">Generic</th> </tr> </thead> <tbody> <tr> <td data-bbox="467 982 824 1024">Amitiza</td> <td data-bbox="824 982 1182 1024">lubiprostone</td> </tr> </tbody> </table> <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The prescriber has stated that the patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer OR B. The prescriber has submitted documentation that the patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat an associated condition related to stage four advanced metastatic cancer [chart notes are required] AND 2. The use of the requested agent is consistent with best practices for the treatment of stage four advanced, metastatic cancer, or an associated condition; supported by peer-reviewed, evidence-based literature; and approved by the United States Food and Drug Administration OR B. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR C. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes are required] OR D. The patient has tried and had an inadequate response to the generic equivalent [chart notes are required] OR E. The generic equivalent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR F. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent [chart notes are required] OR G. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent [chart notes are required] OR H. The generic equivalent is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient’s adherence of care; OR worsen a comorbid condition; OR decrease the patient’s ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes are required] OR 	Brand	Generic	Amitiza	lubiprostone
Brand	Generic				
Amitiza	lubiprostone				

Module	Clinical Criteria for Approval
	<ul style="list-style-type: none"> I. The generic equivalent is not in the best interest of the patient based on medical necessity [chart notes are required] OR J. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as the generic equivalent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR K. There is support for the use of the requested brand agent over the generic equivalent AND <p>4. ONE of the following:</p> <ul style="list-style-type: none"> A. The request is for Relistor (methylnaltrexone) injection OR B. The requested agent is for use in IBS-C or CIC AND ONE of the following: <ul style="list-style-type: none"> 1. BOTH of the following: <ul style="list-style-type: none"> A. ONE of the following: <ul style="list-style-type: none"> 1. The prescriber has stated that the patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer OR 2. The prescriber has submitted documentation that the patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat an associated condition related to stage four advanced metastatic cancer [chart notes are required] AND B. The use of the requested agent is consistent with best practices for the treatment of stage four advanced, metastatic cancer, or an associated condition; supported by peer-reviewed, evidence-based literature; and approved by the United States Food and Drug Administration OR 2. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR 3. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes are required] OR 4. The patient has tried and had an inadequate response to Trulance (plecanatide) and Linzess (linaclotide) [chart notes are required] OR 5. Trulance (plecanatide) and Linzess (linaclotide) were discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR 6. The patient has an intolerance or hypersensitivity to Trulance (plecanatide) and Linzess (linaclotide) that is not expected to occur with the requested agent [chart notes are required] OR 7. The patient has an FDA labeled contraindication to Trulance (plecanatide) and Linzess (linaclotide) that is not expected to occur with the requested agent [chart notes are required] OR 8. Trulance (plecanatide) and Linzess (linaclotide) are expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes are required] OR 9. Trulance (plecanatide) and Linzess (linaclotide) are not in the best interest of the patient based on medical necessity [chart notes are required] OR 10. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as Trulance (plecanatide) and Linzess (linaclotide) and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR C. The requested agent is for use in OIC AND ONE of the following: <ul style="list-style-type: none"> 1. BOTH of the following:

Module	Clinical Criteria for Approval
	<p>A. ONE of the following:</p> <ol style="list-style-type: none"> 1. The prescriber has stated that the patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer OR 2. The prescriber has submitted documentation that the patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat an associated condition related to stage four advanced metastatic cancer [chart notes are required] AND <p>B. The use of the requested agent is consistent with best practices for the treatment of stage four advanced, metastatic cancer, or an associated condition; supported by peer-reviewed, evidence-based literature; and approved by the United States Food and Drug Administration OR</p> <ol style="list-style-type: none"> 2. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR 3. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes are required] OR 4. The patient has tried and had an inadequate response to Symproic (naldemedine) and Movantik (naloxegol) [chart notes are required] OR 5. Symproic (naldemedine) and Movantik (naloxegol) were discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR 6. The patient has an intolerance or hypersensitivity to Symproic (naldemedine) and Movantik (naloxegol) that is not expected to occur with the requested agent [chart notes are required] OR 7. The patient has an FDA labeled contraindication to Symproic (naldemedine) and Movantik (naloxegol) that is not expected to occur with the requested agent [chart notes are required] OR 8. Symproic (naldemedine) and Movantik (naloxegol) are expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes are required] OR 9. Symproic (naldemedine) and Movantik (naloxegol) are not in the best interest of the patient based on medical necessity [chart notes are required] OR 10. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as Symproic (naldemedine) and Movantik (naloxegol) and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] AND <ol style="list-style-type: none"> 5. The patient will NOT be using the requested agent in combination with another constipation agent (i.e., Amitiza/lubiprostone, Ibsrela, Linzess, Motegrity, Movantik, Relistor, Symproic, Trulance) AND 6. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Length of Approval:</p> <p>BCBSOK: 36 months ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>

Module	Clinical Criteria for Approval
	<p>The requested agent will also be approved when the following are met:</p> <ol style="list-style-type: none"> 1. The member resides in Ohio AND 2. The plan is Fully Insured or HIM Shop (SG) AND BOTH of the following <ol style="list-style-type: none"> A. The patient does NOT have any FDA labeled contraindications to the requested agent AND B. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p>Oncology compendia allowed: NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</p> <p>Renewal Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] AND 2. If the patient has an FDA labeled indication, ONE of the following: <ol style="list-style-type: none"> A. The patient's age is within FDA labeling for the requested indication for the requested agent OR B. There is support for using the requested agent for the patient's age for the requested indication AND 3. The patient has had clinical benefit with the requested agent AND 4. The patient will NOT be using the requested agent in combination with another constipation agent in this program for the requested indication (i.e., Amitiza/lubiprostone, Ibsrela, Linzess, Motegrity, Movantik, Relistor, Symproic, Trulance) AND 5. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Length of Approval:</p>

Module	Clinical Criteria for Approval
	BCBSOK: 36 months ALL other plans: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Universa I QL	<p>Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the program quantity limit OR 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication AND 2. There is support for therapy with a higher dose for the requested indication OR B. BOTH of the following: <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication AND 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit OR C. BOTH of the following: <ol style="list-style-type: none"> 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication AND 2. There is support for therapy with a higher dose for the requested indication <p>Length of Approval: 12 months</p>