



Somatostatin Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
04-01-2026

Date of Origin
01-01-2012

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Mycapssa	octreotide acetate cap delayed release	20 MG	M ; N ; O ; Y	N		
Bynfezia pen	octreotide acetate soln pen-injector	2500 MCG/ML	M ; N ; O ; Y	N		
Palsonify	paltusotine hcl tab	20 MG ; 30 MG	M ; N ; O ; Y	N		
Somavert	pegvisomant for inj	10 MG ; 15 MG ; 20 MG ; 25 MG ; 30 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
Bynfezia pen	Octreotide Acetate Soln Pen-Injector 2500 MCG/ML (2.8 ML)	2500 MCG/ML	2	Pens	30	DAYS			
Mycapssa	octreotide acetate cap delayed release	20 MG	120	Capsules	30	DAYS			
Palsonify	paltusotine hcl tab	20 MG	60	Tablets	30	DAYS			
Palsonify	paltusotine hcl tab	30 MG	60	Tablets	30	DAYS			
Somavert	pegvisomant for inj	10 MG ; 15 MG ; 20 MG ; 25 MG ; 30 MG	30	Vials	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Bynfezia pen	octreotide acetate soln pen-injector	2500 MCG/ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; 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 ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Mycapssa	octreotide acetate cap delayed release	20 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; 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 ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Palsonify	paltusotine hcl tab	20 MG ; 30 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; 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 ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Somavert	pegvisomant for inj	10 MG ; 15 MG ; 20 MG ; 25 MG ; 30 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; 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 ; 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

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Bynfezia pen	Octreotide Acetate Soln Pen-Injector 2500 MCG/ML (2.8 ML)	2500 MCG/ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; Jade ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Mycapssa	octreotide acetate cap delayed release	20 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; Jade ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Palsonify	paltusotine hcl tab	30 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; Jade ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ;

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Palsonify	paltusotine hcl tab	20 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; Jade ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Somavert	pegvisomant for inj	10 MG ; 15 MG ; 20 MG ; 25 MG ; 30 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; Jade ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval	
Bynfezia	Preferred Agent(s)	Non-Preferred Target Agent(s)
	octreotide (Sandostatin generic equivalent)	Bynfezia (octreotide)
Initial Evaluation		
Target Agent(s) will be approved when ALL of the following are met:		
<ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The requested agent is eligible for continuation of therapy AND the following: 		

Module	Clinical Criteria for Approval		
	<table border="1" data-bbox="235 184 1227 258"> <tr> <td data-bbox="235 184 1227 218">Agents Eligible for Continuation of Therapy</td> </tr> <tr> <td data-bbox="235 218 1227 258">All target agents are eligible for continuation of therapy</td> </tr> </table> <p data-bbox="375 300 1417 1948"> 1. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 180 days AND is at risk if therapy is changed OR B. BOTH of the following: 1. ONE of the following: A. The patient has a diagnosis of acromegaly AND BOTH of the following: 1. ONE of the following: A. The patient had an inadequate response to surgical resection or pituitary irradiation as indicated by growth hormone and serum IGF-1 that are above the reference ranges OR B. The patient is not a candidate for surgical resection OR C. The requested agent will be used in combination with or following pituitary radiation therapy AND 2. The patient will NOT be using the requested agent in combination with Signifor LAR (pasireotide) OR B. The patient has flushing and/or diarrhea associated with metastatic carcinoid tumors OR C. The patient has profuse watery diarrhea associated with Vasoactive Intestinal Peptide (VIP) secreting tumors OR D. The patient has another FDA labeled indication for the requested agent and route of administration OR E. The patient has another indication that is supported in compendia for the requested agent and route of administration AND 2. ONE of the following: A. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR B. BOTH of the following: 1. ONE of the following: A. 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 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 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 C. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR D. The patient has tried and had an inadequate response to ONE preferred agent [chart notes required] OR E. ONE preferred agent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR F. The patient has an intolerance or hypersensitivity to ONE preferred agent that is not expected to occur with the requested agent [chart notes required] OR </p>	Agents Eligible for Continuation of Therapy	All target agents are eligible for continuation of therapy
Agents Eligible for Continuation of Therapy			
All target agents are eligible for continuation of therapy			

Module	Clinical Criteria for Approval
	<p>G. The patient has an FDA labeled contraindication to ALL preferred agents that is not expected to occur with the requested agent [chart notes required] OR</p> <p>H. ONE preferred agent 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 required] OR</p> <p>I. ONE preferred agent is not in the best interest of the patient based on medical necessity [chart notes required] OR</p> <p>J. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ONE preferred agent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR</p> <p>K. There is support for the use of the requested agent over the preferred agent for the requested indication AND</p> <p>2. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., endocrinologist, oncologist), or the prescriber has consulted with a specialist in the area of the patient’s diagnosis AND</p> <p>3. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>Compendia Allowed: AHFS, NCCN 1, 2a, or 2b recommended use, or DrugDex 1, 2a, or 2b level of evidence</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>The requested agent will also be approved when ONE of the following is met:</p> <p>1. The request is for a BCBS MT Fully Insured or MT HIM member AND</p> <ol style="list-style-type: none"> 1. The patient is under the age of 18 years old AND 2. The patient does NOT have any FDA labeled contraindications to the requested agent AND 3. The patient has an indication that is supported in TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] 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] AND 4. There is support for an age in the patient’s given age bracket in TWO articles from major peer-reviewed professional medical journals as generally safe and effective. The age brackets are: 1. infancy (birth up to, but not including, 2 years of age), 2. childhood (2 years of age through 11 years of age), 3. adolescence (12 years of age through 17 years of age). 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] OR <p>2. ALL of the following:</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 3. The patient does NOT have any FDA labeled contraindications to the requested agent AND

Module	Clinical Criteria for Approval
	<p>4. ONE of the following:</p> <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</p> <p>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. The patient has had clinical benefit with the requested agent (e.g., decrease in symptom severity/frequency, reduction in tumor size, normalized IGF-1 and/or growth hormone levels) AND 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, oncologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 4. If the requested agent is being used for acromegaly, then the patient will NOT be using the requested agent in combination with Signifor LAR (pasireotide) AND 5. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>
Mycapssa (octreotide)	Initial Evaluation

Module	Clinical Criteria for Approval
	<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 requested agent is eligible for continuation of therapy AND the following: <div data-bbox="477 344 1172 422" style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p>Agents Eligible for Continuation of Therapy All target agents are eligible for continuation of therapy</p> </div> <ol style="list-style-type: none"> 1. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 180 days AND is at risk if therapy is changed OR B. The patient has a diagnosis of acromegaly AND BOTH of the following: <ol style="list-style-type: none"> 1. The patient has responded to and tolerated treatment with octreotide or lanreotide AND 2. The patient will NOT be using the requested agent in combination with Signifor LAR (pasireotide) for the requested indication OR C. The patient has another FDA labeled indication for the requested agent and route of administration OR D. The patient has another indication that is supported in compendia for the requested agent and route of administration AND 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, oncologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 3. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>All other plans: 12 months</p> <p>Compendia Allowed: AHFS, NCCN 1, 2a, or 2b recommended use, or DrugDex 1, 2a, or 2b level of evidence</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>The requested agent will also be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The request is for a BCBS MT Fully Insured or MT HIM member AND <ol style="list-style-type: none"> A. The patient is under the age of 18 years old AND B. The patient does NOT have any FDA labeled contraindications to the requested agent AND C. The patient has an indication that is supported in TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] 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] AND D. There is support for an age in the patient's given age bracket in TWO articles from major peer-reviewed professional medical journals as generally safe and effective. The age brackets are: 1. infancy (birth up to, but not including, 2 years of age), 2. childhood (2 years of age through 11 years of age), 3. adolescence (12 years of age through 17 years of age). 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] OR 2. ALL of the following:

Module	Clinical Criteria for Approval
	<p>A. The member resides in Ohio AND B. The plan is Fully Insured or HIM Shop (SG) AND C. The patient does NOT have any FDA labeled contraindications to the requested agent AND D. ONE of the following:</p> <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</p> <p>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. The patient has had clinical benefit with the requested agent (e.g., decrease in symptom severity/frequency, reduction in tumor size, normalized IGF-1 and/or growth hormone levels) AND 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, oncologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 4. If the requested agent is being used for acromegaly, then the patient will NOT be using the requested agent in combination with Signifor LAR (pasireotide) AND 5. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>

Module	Clinical Criteria for Approval			
Palsonify (paltrusotine)	Preferred Agent(s)	Non-Preferred Target Agent(s)		
	Any generic octreotide agent	Palsonify (paltrusotine)		
	Initial Evaluation			
Target Agent(s) will be approved when ALL of the following are met:				
<ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> 1. The requested agent is eligible for continuation of therapy AND the following: 				
<table border="1" style="width: 100%; text-align: center;"> <tr> <td>Agents Eligible for Continuation of Therapy</td> </tr> <tr> <td>All target agents are eligible for continuation of therapy</td> </tr> </table>			Agents Eligible for Continuation of Therapy	All target agents are eligible for continuation of therapy
Agents Eligible for Continuation of Therapy				
All target agents are eligible for continuation of therapy				
<ol style="list-style-type: none"> A. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 180 days AND is at risk if therapy is changed OR 2. BOTH of the following: <ol style="list-style-type: none"> A. ONE of the following: <ol style="list-style-type: none"> 1. The patient has a diagnosis of acromegaly AND ALL of the following: <ol style="list-style-type: none"> A. ONE of the following: <ol style="list-style-type: none"> 1. The patient had an inadequate response to surgical resection as indicated by growth hormone and serum IGF-1 that are above the reference ranges OR 2. The patient is not a candidate for surgical resection OR 3. The requested agent will be used in combination with or following pituitary radiation therapy AND B. The patient will NOT be using the requested agent in combination with Signifor LAR (pasireotide) for the requested indication AND C. ONE of the following: <ol style="list-style-type: none"> 1. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR 2. BOTH of the following: <ol style="list-style-type: none"> A. ONE of the following: <ol style="list-style-type: none"> 1. 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 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 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 				

Module	Clinical Criteria for Approval
	<p style="text-align: center;">by the United States Food and Drug Administration OR</p> <ol style="list-style-type: none"> 3. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR 4. BOTH of the following: <ol style="list-style-type: none"> A. ONE of the following: <ol style="list-style-type: none"> 1. The patient has tried and had an inadequate response to cabergoline [chart notes required] OR 2. Cabergoline was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR 3. The patient has an intolerance or hypersensitivity to cabergoline [chart notes required] OR 4. The patient has an FDA labeled contraindication to cabergoline [chart notes required] OR 5. Cabergoline 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 required] OR 6. Cabergoline is not in the best interest of the patient based on medical necessity [chart notes required] OR 7. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as cabergoline and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR 8. There is support for use of the requested agent over cabergoline AND B. ONE of the following: <ol style="list-style-type: none"> 1. The patient has tried and had an inadequate response to ONE preferred agent [chart notes required] OR

Module	Clinical Criteria for Approval
	<ol style="list-style-type: none"> 2. ONE preferred agent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR 3. The patient has an intolerance or hypersensitivity to ONE preferred agent [chart notes required] OR 4. The patient has an FDA labeled contraindication to ALL preferred agents [chart notes required] OR 5. ONE preferred agent 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 required] OR 6. ONE preferred agent is not in the best interest of the patient based on medical necessity [chart notes required] OR 7. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ONE preferred agent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR 8. The patient has tried and had an inadequate response to another somatostatin analog agent (e.g., Mycapssa, Somavert, Somatuline depot/lanreotide, or Sandostatin LAR) OR <ol style="list-style-type: none"> 2. The patient has another FDA labeled indication for the requested agent and route of administration OR 3. The patient has another indication that is supported in compendia for the requested agent and route of administration AND <p>B. If the patient has an FDA labeled indication, then ONE of the following:</p> <ol style="list-style-type: none"> 1. The patient's age is within FDA labeling for the requested indication for the requested agent OR 2. There is support for using the requested agent for the patient's age for the requested indication AND <ol style="list-style-type: none"> 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, oncologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 3. The patient does NOT have any FDA labeled contraindications to the requested agent

Module	Clinical Criteria for Approval
	<p>Length of Approval:</p> <p>BCBSOK: 36 months:</p> <p>ALL other plans: 12 months</p> <p>Compendia Allowed: AHFS, NCCN 1, 2a, or 2b recommended use, or DrugDex 1, 2a, or 2b level of evidence</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>The requested agent will also be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The request is for a BCBS MT Fully Insured or MT HIM member AND <ol style="list-style-type: none"> 1. The patient is under the age of 18 years old AND 2. The patient does NOT have any FDA labeled contraindications to the requested agent AND 3. The patient has an indication that is supported in TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] 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] AND 4. There is support for an age in the patient’s given age bracket in TWO articles from major peer-reviewed professional medical journals as generally safe and effective. The age brackets are: 1. infancy (birth up to, but not including, 2 years of age), 2. childhood (2 years of age through 11 years of age), 3. adolescence (12 years of age through 17 years of age). 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] OR 2. ALL of the following: <ol style="list-style-type: none"> 1. The member resides in Ohio AND 2. The plan is Fully Insured or HIM Shop (SG) AND 3. The patient does NOT have any FDA labeled contraindications to the requested agent AND 4. 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>

Module	Clinical Criteria for Approval									
	<p>BCBSOK: 36 months:</p> <p>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. The patient has had clinical benefit with the requested agent (e.g., decrease in symptom severity/frequency, reduction in tumor size, normalized IGF-1 and/or growth hormone levels) AND 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, oncologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 4. If the requested agent is being used for acromegaly, then the patient will NOT be using the requested agent in combination with Signifor LAR (pasireotide) AND 5. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Length of Approval:</p> <p>BCBSOK: 36 months:</p> <p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>									
somavert (pegvisomant)	<table border="1" data-bbox="235 1234 950 1522"> <thead> <tr> <th data-bbox="235 1234 592 1304">Preferred Target Agent(s)</th> <th data-bbox="592 1234 950 1304">Non-Preferred Target Agent(s)</th> </tr> </thead> <tbody> <tr> <td data-bbox="235 1304 592 1459">lanreotide deep subcutaneous injection (Somatuline Depot generic equivalent)</td> <td data-bbox="592 1304 950 1459">Somavert</td> </tr> <tr> <td data-bbox="235 1459 592 1522">octreotide gluteal intramuscular injection</td> <td data-bbox="592 1459 950 1522"></td> </tr> </tbody> </table> <p>Initial Evaluation</p> <p>Target agents will be approved when ALL the following are met:</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The requested agent is eligible for continuation of therapy AND the following: <table border="1" data-bbox="430 1795 1221 1875"> <thead> <tr> <th data-bbox="430 1795 1221 1837">Agents Eligible for Continuation of Therapy</th> </tr> </thead> <tbody> <tr> <td data-bbox="430 1837 1221 1875">All target agents are eligible for continuation of therapy</td> </tr> </tbody> </table>		Preferred Target Agent(s)	Non-Preferred Target Agent(s)	lanreotide deep subcutaneous injection (Somatuline Depot generic equivalent)	Somavert	octreotide gluteal intramuscular injection		Agents Eligible for Continuation of Therapy	All target agents are eligible for continuation of therapy
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	<ol style="list-style-type: none"> 1. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 180 days AND is at risk if therapy is changed OR B. The patient has a diagnosis of acromegaly AND ALL of the following: <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient had an inadequate response to surgical resection or pituitary radiation therapy as indicated by growth hormone and serum IGF-1 that are above the reference ranges OR B. The patient is not a candidate for surgical resection OR C. The requested agent will be used in combination with or following pituitary radiation therapy AND 2. ONE of the following: <ol style="list-style-type: none"> A. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR B. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR C. The patient has tried and had an inadequate response to ONE preferred agent [chart notes required] AND ONE of the following: <ol style="list-style-type: none"> 1. The dose and/or frequency of the preferred agent has been increased to the maximally tolerated dose OR 2. The patient has preexisting impaired glucose metabolism OR D. ONE preferred agent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR E. The patient has an intolerance or hypersensitivity to ONE preferred agent [chart notes required] OR F. The patient has an FDA labeled contraindication to ALL preferred agents [chart notes required] OR G. ONE preferred agent 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 required] OR H. ONE preferred agent is not in the best interest of the patient based on medical necessity [chart notes required] OR I. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ONE preferred agent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR J. The patient is currently using ONE preferred agent and the requested agent will be used as add on (adjunctive) therapy OR K. There is support for the use of the requested agent over ALL preferred agents OR 3. The patient will NOT be using the requested agent in combination with Signifor LAR (pasireotide) for the requested indication OR C. The patient has another FDA labeled indication for the requested agent and route of administration OR D. The patient has another indication that is supported in compendia for the requested agent and route of administration AND

Module	Clinical Criteria for Approval
	<p>2. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., endocrinologist, oncologist), or the prescriber has consulted with a specialist in the area of the patient’s diagnosis AND</p> <p>3. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months:</p> <p>ALL other plans: 12 months</p> <p>Compendia Allowed: AHFS, NCCN 1, 2a, or 2b recommended use, or DrugDex 1, 2a, or 2b level of evidence</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>The requested agent will also be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The request is for a BCBS MT Fully Insured or MT HIM member AND <ol style="list-style-type: none"> A. The patient is under the age of 18 years old AND B. The patient does NOT have any FDA labeled contraindications to the requested agent AND C. The patient has an indication that is supported in TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] 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] AND D. There is support for an age in the patient’s given age bracket in TWO articles from major peer-reviewed professional medical journals as generally safe and effective. The age brackets are: 1. infancy (birth up to, but not including, 2 years of age), 2. childhood (2 years of age through 11 years of age), 3. adolescence (12 years of age through 17 years of age). 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] OR 2. ALL of the following: <ol style="list-style-type: none"> A. The member resides in Ohio AND B. The plan is Fully Insured or HIM Shop (SG) AND C. The patient does NOT have any FDA labeled contraindications to the requested agent AND D. 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>

Module	Clinical Criteria for Approval
	<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:</p> <p>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. The patient has had clinical benefit (e.g., decrease in symptom severity/frequency, reduction in tumor size, normalized IGF-1 and/or growth hormone levels) AND 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, oncologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 4. If the requested agent is being used for acromegaly, then the patient will NOT be using the requested agent in combination with Signifor LAR (pasireotide) AND 5. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Length of Approval:</p> <p>BCBSOK: 36 months:</p> <p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<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:

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	<ol style="list-style-type: none"><li data-bbox="467 180 1386 239">1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication AND<li data-bbox="467 239 1308 298">2. There is support for therapy with a higher dose for the requested indication <p data-bbox="228 331 638 365">Length of Approval: 12 months</p>