



Growth Hormone Prior Authorization Program Summary

POLICY REVIEW CYCLE

Effective Date
02-15-2026

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
Genotropin ; Genotropin miniquick ; Humatrope ; Ngenla ; Norditropin flexpro ; Nutropin aq nuspin 10 ; Nutropin aq nuspin 20 ; Nutropin aq nuspin 5 ; Omnitrope ; Saizen ; Serostim ; Skytrofa ; Sogroya ; Zomacton ; Zorbtive		0.2 MG ; 0.4 MG ; 0.6 MG ; 0.7 MG ; 0.8 MG ; 1 MG ; 1.2 MG ; 1.4 MG ; 1.6 MG ; 1.8 MG ; 10 MG ; 10 MG/1.5ML ; 11 MG/2ML ; 11 MG ; 12 MG ; 13.3 MG ; 15 MG/1.5ML ; 2 MG ; 2.1 MG ; 2.5 MG ; 20 MG/2ML ; 24 MG ; 24 MG/1.2ML ; 3 MG ; 3.6 MG ; 30 MG/3ML ; 4 MG ; 4.3 MG ; 5 MG ; 5 MG/1.5ML ; 5 MG/2ML ; 5.2 MG ; 5.8 MG ; 6 MG ; 6.3 MG ; 60 MG/1.2ML ; 7.6 MG ; 8.8 MG ; 9.1 MG	M ; N ; O ; Y	N		

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Genotropin ; Genotropin miniquick ; Humatrope ; Ngenla ; Norditropin flexpro ; Nutropin aq nuspin 10 ; Nutropin aq nuspin 20 ; Nutropin aq nuspin 5 ; Omnitrope ; Saizen ; Serostim ; Skytrofa ; Sogroya ; Zomacton ; Zorbtive		0.2 MG ; 0.4 MG ; 0.6 MG ; 0.7 MG ; 0.8 MG ; 1 MG ; 1.2 MG ; 1.4 MG ; 1.6 MG ; 1.8 MG ; 10 MG ; 10 MG/1.5ML ; 10 MG/2ML ; 11 MG ; 12 MG ; 13.3 MG ; 15 MG/1.5ML ; 2 MG ; 2.1 MG ; 2.5 MG ; 20 MG/2ML ; 24 MG ; 24 MG/1.2ML ; 3 MG ; 3.6 MG ; 30 MG/3ML ; 4 MG ; 4.3 MG ; 5 MG ; 5 MG/1.5ML ; 5 MG/2ML ; 5.2 MG ; 5.8 MG ; 6 MG ; 6.3 MG ; 60 MG/1.2ML ; 7.6 MG ; 8.8 MG ; 9.1 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 ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval		
Adults: Long and Short Acting Growth Hormone	Formulation	Preferred Target Agent(s)	Non-Preferred Target Agent(s)
	Short-Acting Agent(s)	Genotropin, Genotropin MiniQuick (somatropin) Omnitrope (somatropin)	Humatrope (somatropin) Norditropin FlexPro (somatropin) Nutropin AQ NuSpin (somatropin) Saizen, Saizenprep (somatropin) Serostim (somatropin) Zomacton (somatropin) Zorbtive (somatropin)
	Long-Acting Agent(s)	Skytrofa (lonapegsomatropin-tcgd)	Ngenla (somatrogon-ghla) Sogroya (somapacitan-beco)
Adults – Initial Evaluation			
Target Agent(s) will be approved when ALL of the following are met:			
<ol style="list-style-type: none"> 1. The patient is an adult (as defined by the prescriber) AND 2. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of AIDS wasting/cachexia AND ALL of the following: <ol style="list-style-type: none"> 1. The requested agent is a short-acting growth hormone (GH) AND 2. The patient is currently treated with antiretroviral therapy AND 3. The patient will continue antiretroviral therapy in combination with the requested agent AND 4. BOTH of the following: <ol style="list-style-type: none"> A. ONE of the following [chart notes required]: <ol style="list-style-type: none"> 1. The patient has had ONE of the following: <ol style="list-style-type: none"> A. Unintentional weight loss greater than or equal to 10% over 12 months OR B. Unintentional weight loss greater than or equal to 7.5% over 6 months OR 2. The patient has a body cell mass (BCM) loss greater than or equal to 5% within 6 months OR 3. The patient’s sex is male and has a BCM less than 35% of total body weight and body mass index (BMI) less than 27 kg/m² OR 4. The patient’s sex is female and has a BCM less than 23% of total body weight and BMI less than 27 kg/m² OR 5. There is support that the patient's BCM is less than 35% or less than 23% (based on sex) and BMI less than 27 kg/m² are medically appropriate for diagnosing AIDS wasting/cachexia OR 6. The patient’s BMI is less than 20 kg/m² AND B. All other causes of weight loss have been ruled out OR B. The patient has a diagnosis of short bowel syndrome (SBS) AND BOTH of the following: <ol style="list-style-type: none"> 1. The requested agent is a short-acting growth hormone (GH) AND 			

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	<p>2. The patient is receiving specialized nutritional support [chart notes required] OR</p> <p>C. The patient has a diagnosis of growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous growth hormone (GH) AND the patient has ONE of the following [chart notes required]:</p> <ol style="list-style-type: none"> 1. Had a diagnosis of childhood-onset GHD AND has failed at least ONE GH stimulation test as an adult OR 2. Low insulin-like growth factor-1 (IGF-1) level AND ONE of the following: <ol style="list-style-type: none"> A. Organic hypothalamic-pituitary disease OR B. Pituitary structural lesion or trauma OR C. Panhypopituitarism or multiple (greater than or equal to 3) pituitary hormone deficiency (MPHD) OR 3. An established causal genetic mutation OR hypothalamic-pituitary structural defect other than ectopic posterior pituitary OR 4. Failed at least TWO GH stimulation tests as an adult OR 5. Failed at least ONE GH stimulation test as an adult AND the patient has an organic pituitary disease OR <p>D. The patient has another FDA labeled indication for the requested agent and route of administration OR</p> <p>E. The patient has another indication that is supported in compendia for the requested agent and route of administration AND</p> <p>3. The request is for a long-acting growth hormone (GH) agent AND if the patient has an FDA labeled indication, then ONE of the following:</p> <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 <p>4. ONE of the following:</p> <ol style="list-style-type: none"> A. The request is for a short-acting GH agent, then ONE of the following: <ol style="list-style-type: none"> 1. The request is for a preferred short-acting agent OR 2. The request is for a non-preferred short-acting agent AND 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 are required] OR C. The patient has tried and had an inadequate response to ONE preferred short-acting agent [chart notes are required] OR D. ONE preferred short-acting agent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR E. The patient has an intolerance or hypersensitivity to ONE preferred short-acting agent that is NOT expected to occur with the requested agent (medical records required) OR F. The patient has an FDA labeled contraindication to ALL preferred short-acting agent(s) that is NOT expected to occur with the requested agent (medical records required) OR G. ONE preferred short-acting 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 are required] OR H. ONE preferred short-acting agent is not in the best interest of the patient based on medical necessity [chart notes are required] OR I. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as a preferred agent and that prescription drug was discontinued due

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	<p>to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR</p> <p>J. There is support for the efficacy of the requested agent over ALL preferred short-acting agent(s) for the requested indication (medical records required) OR</p> <p>B. The request is for a long-acting GH agent, then ALL of the following:</p> <ol style="list-style-type: none"> 1. The requested agent is FDA labeled for the requested indication 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 are required] OR C. The patient has tried and had an inadequate response to ONE preferred short-acting agent [chart notes are required] OR D. ONE preferred short-acting agent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR E. The patient received at least 12 months of therapy with a preferred short-acting agent OR F. The patient has an intolerance or hypersensitivity to ONE preferred short-acting agent that is NOT expected to occur with the requested agent (medical record required) OR G. The patient has an FDA labeled contraindication to ALL preferred short-acting agent(s) that is NOT expected to occur with the requested agent (medical record required) OR H. ONE preferred short-acting 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 are required] OR I. ONE preferred short-acting agent 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 a preferred agent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] AND 3. ONE of the following: <ol style="list-style-type: none"> A. The requested agent is a preferred long-acting agent OR B. The requested agent is a non-preferred long-acting agent AND the preferred long-acting agent(s) are NOT FDA labeled for the requested indication OR 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. 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 3. Received at least 12 months of therapy with a preferred long-acting agent OR 4. The patient has tried and had an inadequate response to a preferred long-acting GH agent [chart notes are required] OR 5. ONE preferred long-acting agent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR

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	<p>6. An intolerance or hypersensitivity to ONE preferred long-acting agent that is NOT expected to occur with the requested agent (medical record required) OR</p> <p>7. An FDA labeled contraindication to ALL preferred long-acting agent(s) that is NOT expected to occur with the requested agent (medical record required) OR</p> <p>8. ONE preferred long-acting 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 are required] OR</p> <p>9. ONE preferred long-acting agent is not in the best interest of the patient based on medical necessity [chart notes are required] OR</p> <p>10. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ONE preferred long-acting agent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] AND</p> <p>5. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND</p> <p>7. The requested quantity (dose) is within FDA labeling or supported in compendia for the requested indication</p> <p>Compendia Allowed: AHFS or DrugDex 1, 2a, or 2b level of evidence</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>BCBSIL and BCBSMT: 12 months</p> <p>BCBSNM: SBS - 3 months; AIDS wasting/cachexia - 3 months; All other indications - 12 months</p> <p>ALL other plans: SBS - 4 weeks; AIDS wasting/cachexia - 12 weeks; All other indications - 12 months</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

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	<p>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> <p>2. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following:</p> <ol style="list-style-type: none"> 1. The patient does NOT have any FDA labeled contraindications to the requested agent AND 2. The requested indication is a rare disease AND 3. 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 <p>3. 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 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> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>Adults – 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 therapy with growth hormone (GH) through the plan’s Prior Authorization process (Note: patients not previously approved for therapy with GH will require initial evaluation review) AND 2. The patient is an adult (as defined by the prescriber) AND 3. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of short bowel syndrome (SBS) AND has had clinical benefit with the requested agent OR

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	<p>B. The patient has a diagnosis of AIDS wasting/cachexia AND ALL of the following:</p> <ol style="list-style-type: none"> 1. The patient is currently treated with antiretroviral therapy AND 2. The patient will continue antiretroviral therapy in combination with the requested agent AND 3. The patient has had clinical benefit with the requested agent (i.e., an increase in weight or weight stabilization) OR <p>C. The patient has a diagnosis of growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous GH AND BOTH of the following:</p> <ol style="list-style-type: none"> 1. The patient's insulin-like growth factor-1 (IGF-1) level has been evaluated to confirm the appropriateness of the current dose AND 2. The patient has had clinical benefit with the requested agent (i.e., body composition, hip-to-waist ratio, cardiovascular health, bone mineral density, serum cholesterol, physical strength, or quality of life) OR <p>D. The patient has a diagnosis other than SBS, AIDS wasting/cachexia, GHD, or growth failure due to inadequate secretion of endogenous GH AND has had clinical benefit with the requested agent AND</p> <p>4. ONE of the following:</p> <p>A. The request is for a short-acting GH agent, then ONE of the following:</p> <ol style="list-style-type: none"> 1. The request is for a preferred short-acting agent OR 2. The request is for a non-preferred short-acting agent AND 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 are required] OR C. The patient has tried and had an inadequate response to ONE preferred short-acting agent [chart notes are required] OR D. ONE preferred short-acting agent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR E. The patient has an intolerance or hypersensitivity to ONE preferred short-acting agent that is NOT expected to occur with the requested agent (medical records required) OR F. The patient has an FDA labeled contraindication to ALL preferred short-acting agent(s) that is NOT expected to occur with the requested agent (medical records required) OR G. ONE preferred short-acting 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 are required] OR H. ONE preferred short-acting agent is not in the best interest of the patient based on medical necessity [chart notes are required] OR I. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as a preferred agent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR J. There is support for the efficacy of the requested agent over ALL preferred short-acting agent(s) for the requested indication (medical records required) OR <p>B. The request is for a long-acting GH agent, then ALL of the following:</p> <ol style="list-style-type: none"> 1. The requested agent is FDA labeled for the requested indication 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 are required] OR

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	<ul style="list-style-type: none"> C. The patient has tried and had an inadequate response to ONE preferred short-acting agent [chart notes are required] OR D. ONE preferred short-acting agent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR E. The patient received at least 12 months of therapy with a preferred short-acting agent OR F. The patient has an intolerance or hypersensitivity to ONE preferred short-acting agent that is NOT expected to occur with the requested agent (medical record required) OR G. The patient has an FDA labeled contraindication to ALL preferred short-acting agent(s) that is NOT expected to occur with the requested agent (medical record required) OR H. ONE preferred short-acting 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 are required] OR I. ONE preferred short-acting agent 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 a preferred agent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] AND <p>3. ONE of the following:</p> <ul style="list-style-type: none"> A. The requested agent is a preferred long-acting agent OR B. The requested agent is a non-preferred long-acting agent AND the preferred long-acting agent(s) are NOT FDA labeled for the requested indication OR C. ONE of the following: <ul 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. 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 3. Received at least 12 months of therapy with a preferred long-acting agent OR 4. The patient has tried and had an inadequate response to a preferred long-acting GH agent [chart notes are required] OR 5. ONE preferred long-acting agent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR 6. An intolerance or hypersensitivity to ONE preferred long-acting agent that is NOT expected to occur with the requested agent (medical record required) OR 7. An FDA labeled contraindication to ALL preferred long-acting agent(s) that is NOT expected to occur with the requested agent (medical record required) 8. ONE preferred long-acting 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

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	<p>activities; OR cause an adverse reaction or cause physical or mental harm [chart notes are required] OR</p> <p>9. ONE preferred long-acting agent is not in the best interest of the patient based on medical necessity [chart notes are required] OR</p> <p>10. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ONE preferred long-acting agent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] AND</p> <p>5. The patient is being monitored for adverse effects of GH AND</p> <p>6. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>7. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., endocrinologist), or the prescriber has consulted with a specialist in the area of the patient’s diagnosis AND</p> <p>8. The requested quantity (dose) is within FDA labeling or supported in compendia for the requested indication</p> <p>Compendia Allowed: AHFS or DrugDex 1, 2a, or 2b level of evidence</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>BCBSIL and BCBSMT: 12 months</p> <p>BCBSNM: SBS - 3 months; AIDS wasting/cachexia - 3 months; All other indications - 12 months</p> <p>ALL other plans: SBS - 4 weeks; AIDS wasting/cachexia - 12 weeks; All other indications - 12 months</p>

Children : Long-Acting Growth Hormone	<table border="1"> <thead> <tr> <th data-bbox="228 1205 565 1272">Formulation</th> <th data-bbox="565 1205 898 1272">Preferred Target Agent(s)</th> <th data-bbox="898 1205 1227 1272">Non-Preferred Target Agent(s)</th> </tr> </thead> <tbody> <tr> <td data-bbox="228 1272 565 1572"> Short-Acting Agent(s) </td> <td data-bbox="565 1272 898 1572"> Genotropin, Genotropin MiniQuick (somatropin) Omnitrope (somatropin) </td> <td data-bbox="898 1272 1227 1572"> Humatrope (somatropin) Norditropin FlexPro (somatropin) Nutropin AQ NuSpin (somatropin) Saizen, Saizenprep (somatropin) Serostim (somatropin) Zomacton (somatropin) Zorbtive (somatropin) </td> </tr> <tr> <td data-bbox="228 1572 565 1696"> Long-Acting Agent(s) </td> <td data-bbox="565 1572 898 1696"> Skytrofa (lonapegsomatropin-tcgd) </td> <td data-bbox="898 1572 1227 1696"> Ngenla (somatrogonghla) Sogroya (somapacitanbeco) </td> </tr> </tbody> </table>	Formulation	Preferred Target Agent(s)	Non-Preferred Target Agent(s)	Short-Acting Agent(s)	Genotropin, Genotropin MiniQuick (somatropin) Omnitrope (somatropin)	Humatrope (somatropin) Norditropin FlexPro (somatropin) Nutropin AQ NuSpin (somatropin) Saizen, Saizenprep (somatropin) Serostim (somatropin) Zomacton (somatropin) Zorbtive (somatropin)	Long-Acting Agent(s)	Skytrofa (lonapegsomatropin-tcgd)	Ngenla (somatrogonghla) Sogroya (somapacitanbeco)	<p>Children – Initial Evaluation</p>
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Long-Acting Agent(s)	Skytrofa (lonapegsomatropin-tcgd)	Ngenla (somatrogonghla) Sogroya (somapacitanbeco)									
<p>Target Agent(s) will be approved when ALL of the following are met:</p>	<ol style="list-style-type: none"> 1. The patient is a child (as defined by the prescriber) AND 2. ONE of the following: 										

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	<p>A. The patient has a diagnosis of growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous growth hormone (GH) AND the patient has ONE of the following:</p> <ol style="list-style-type: none"> 1. Extreme short stature (e.g., height less than or equal to -3 SD), normal nutrition, significantly reduced insulin-like growth factor-1 (IGF-1) and IGFBP-3 (e.g., less than -2 SD), and delayed bone age [chart notes required] OR 2. BOTH of the following: <ol style="list-style-type: none"> A. The patient has ONE of the following [chart notes required]: <ol style="list-style-type: none"> 1. Height greater than 2 SD below the mean for age and sex OR 2. Height greater than 1.5 SD below the mid-parental height OR 3. Decrease in height SD of greater than 0.5 SD over one year in children greater than 2 years of age OR 4. Height velocity (HV) greater than 2 SD below the mean over one year or greater than 1.5 SD sustained over two years OR 5. Height-for-age curve that has deviated downward across two major height percentile curves (e.g., from above the 25th percentile to below the 10th percentile) OR 6. BOTH of the following: <ol style="list-style-type: none"> A. The patient's age is 2-4 years AND B. The patient has a HV less than 5.5 cm/year (less than 2.2 inches/year) OR 7. BOTH of the following: <ol style="list-style-type: none"> A. The patient's age is 4-6 years AND B. The patient has a HV less than 5 cm/year (less than 2 inches/year) OR 8. The patient's age is 6 years to puberty AND ONE of the following: <ol style="list-style-type: none"> A. The patient's sex is male and HV is less than 4 cm/year (less than 1.6 inches/year) OR B. The patient's sex is female and HV is less than 4.5 cm/year (less than 1.8 inches/year) AND B. The patient has ONE of the following: <ol style="list-style-type: none"> 1. Failed at least TWO GH stimulation tests (e.g., peak GH value of less than 10 mcg/L after stimulation, or otherwise considered abnormal as determined by testing lab) OR 2. Failed at least ONE GH stimulation test (e.g., peak GH value of less than 10 mcg/L after stimulation, or otherwise considered abnormal as determined by testing lab) AND ONE of the following: <ol style="list-style-type: none"> A. Pathology of the central nervous system OR B. History of irradiation OR C. Other pituitary hormone defects (e.g., multiple pituitary hormone deficiency [MPHD]) OR D. A genetic defect OR 3. A pituitary abnormality and a known deficit of at least ONE other pituitary hormone OR <p>B. The patient has another FDA labeled indication for the requested agent and route of administration OR</p> <p>C. The patient has another indication that is supported in compendia for the requested agent and route of administration AND</p> <p>3. If the patient has an FDA labeled indication, then ONE of the following:</p> <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 <p>4. ALL of the following:</p> <ol style="list-style-type: none"> A. The requested agent is FDA labeled for the requested indication AND

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	<p>B. ONE of the following:</p> <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. The patient is currently being treated with the requested agent AND the patient is currently stable on the requested agent [chart notes required] OR 3. The patient has received at least 12 months of therapy with a preferred short-acting GH agent OR 4. The patient has tried and had an inadequate response to ONE preferred short-acting agent [chart notes required] OR 5. ONE preferred short-acting agent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR 6. The patient has an intolerance or hypersensitivity to ONE preferred short-acting agent that is NOT expected to occur with the requested agent (medical record required) OR 7. The patient has an FDA labeled contraindication to ALL preferred short-acting agent(s) that is NOT expected to occur with the requested agent (medical record required) OR 8. ONE preferred short-acting 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 9. ONE preferred short-acting agent is not in the best interest of the patient based on medical necessity [chart notes required] OR 10. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ONE preferred short-acting agent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] AND <p>C. ONE of the following:</p> <ol style="list-style-type: none"> 1. The requested agent is a preferred long-acting GH agent OR 2. The requested agent is a non-preferred long-acting agent AND 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 received at least 12 months of therapy with a preferred long-acting agent OR D. The patient has tried and had an inadequate response to ONE preferred long-acting agent [chart notes required] OR E. ONE preferred long-acting 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 long-acting agent that is NOT expected to occur with the requested agent (medical record required) OR G. The patient has an FDA labeled contraindication to ALL preferred long-acting agent(s) that is NOT expected to occur with the requested agent (medical record required) OR H. ONE preferred long-acting 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

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	<p>activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR</p> <ol style="list-style-type: none"> I. ONE preferred long-acting agent is not in the best interest of the patient based on medical necessity [chart notes required] OR J. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ONE preferred long-acting agent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] AND <ol style="list-style-type: none"> 5. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., endocrinologist), or the prescriber has consulted with a specialist in the area of the patient’s diagnosis AND 6. The patient does NOT have any FDA labeled contraindications to the requested agent AND 7. The requested quantity (dose) is within FDA labeling or supported in compendia for the requested indication <p>Compendia Allowed: AHFS or DrugDex 1, 2a, or 2b level of evidence</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</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. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following: <ol style="list-style-type: none"> 1. The patient does NOT have any FDA labeled contraindications to the requested agent AND 2. The requested indication is a rare disease AND 3. 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. 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

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	<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>Children – 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 therapy with growth hormone (GH) through the plan’s Prior Authorization process (Note: patients not previously approved for therapy with GH will require initial evaluation review) AND 2. The patient is a child (as defined by the prescriber) AND 3. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous GH AND BOTH of the following: <ol style="list-style-type: none"> 1. The patient does NOT have closed epiphyses AND 2. The patient’s height has increased greater than or equal to 2 cm over the previous year with GH therapy OR B. The patient has a diagnosis other than GHD or growth failure due to inadequate secretion of endogenous GH AND has had clinical benefit with the requested agent AND 4. ALL of the following: <ol style="list-style-type: none"> A. The requested agent is FDA labeled for the requested indication AND B. 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. The patient is currently being treated with the requested agent AND the patient is currently stable on the requested agent [chart notes required] OR 3. The patient has received at least 12 months of therapy with a preferred short-acting GH agent OR 4. The patient has tried and had an inadequate response to ONE preferred short-acting agent [chart notes required] OR 5. ONE preferred short-acting agent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR

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	<p>6. The patient has an intolerance or hypersensitivity to ONE preferred short-acting agent that is NOT expected to occur with the requested agent (medical record required) OR</p> <p>7. The patient has an FDA labeled contraindication to ALL preferred short-acting agent(s) that is NOT expected to occur with the requested agent (medical record required) OR</p> <p>8. ONE preferred short-acting 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>9. ONE preferred short-acting agent is not in the best interest of the patient based on medical necessity [chart notes required] OR</p> <p>10. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ONE preferred short-acting agent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] AND</p> <p>c. ONE of the following:</p> <ol style="list-style-type: none"> 1. The requested agent is a preferred long-acting GH agent OR 2. The requested agent is a non-preferred long-acting agent AND 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 received at least 12 months of therapy with a preferred long-acting agent OR D. The patient has tried and had an inadequate response to ONE preferred long-acting agent [chart notes required] OR E. ONE preferred long-acting 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 long-acting agent that is NOT expected to occur with the requested agent (medical record required) OR G. The patient has an FDA labeled contraindication to ALL preferred long-acting agent(s) that is NOT expected to occur with the requested agent (medical record required) OR H. ONE preferred long-acting 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 I. ONE preferred long-acting agent is not in the best interest of the patient based on medical necessity [chart notes required] OR J. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ONE preferred long-acting agent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] AND <p>5. The patient is being monitored for adverse effects of GH AND</p> <p>6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND</p>

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	<p>7. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>8. The requested quantity (dose) is within FDA labeling or supported in compendia for the requested indication</p> <p>Compendia Allowed: AHFS or DrugDex 1 or 2a level of evidence</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p>

Children : Short-Acting Growth Hormone	<table border="1"> <thead> <tr> <th data-bbox="228 567 565 674">Formulations</th> <th data-bbox="565 567 899 674">Preferred Target Agent(s)</th> <th data-bbox="899 567 1229 674">Non-Preferred Target Agent(s)</th> </tr> </thead> <tbody> <tr> <td data-bbox="228 674 565 976">Short-Acting Agent(s)</td> <td data-bbox="565 674 899 976">Genotropin, Genotropin MiniQuick (somatropin) Omnitrope (somatropin)</td> <td data-bbox="899 674 1229 976">Humatrope (somatropin) Norditropin FlexPro (somatropin) Nutropin AQ NuSpin (so matropin) Saizen, Saizenprep (somatropin) Serostim (somatropin) Zomacton (somatropin) Zorbtive (somatropin)</td> </tr> </tbody> </table>	Formulations	Preferred Target Agent(s)	Non-Preferred Target Agent(s)	Short-Acting Agent(s)	Genotropin, Genotropin MiniQuick (somatropin) Omnitrope (somatropin)	Humatrope (somatropin) Norditropin FlexPro (somatropin) Nutropin AQ NuSpin (so matropin) Saizen, Saizenprep (somatropin) Serostim (somatropin) Zomacton (somatropin) Zorbtive (somatropin)
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<p>Children – 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. The patient is a child (as defined by the prescriber) AND 2. ONE of the following: <ol style="list-style-type: none"> A. ALL of the following: <ol style="list-style-type: none"> 1. The patient is a newborn (less than or equal to 4 months of age) with hypoglycemia AND 2. The patient has a serum growth hormone (GH) concentration less than or equal to 5 mcg/L [chart notes required] AND 3. ONE of the following: <ol style="list-style-type: none"> A. Congenital pituitary abnormality (e.g., ectopic posterior pituitary and pituitary hypoplasia with abnormal stalk) OR B. Deficiency of at least ONE additional pituitary hormone OR B. ALL of the following: <ol style="list-style-type: none"> 1. The patient is a newborn (less than or equal to 4 months of age) with hypoglycemia AND 2. The patient has a growth hormone (GH) concentration of less than 20 mcg/L [chart notes required] AND 3. The patient does NOT have a known metabolic disorder AND 4. The patient has a reduced insulin-like growth factor binding protein 3 (IGFBP-3) level (e.g., less than -2 SD) OR C. The patient has ONE of the following diagnoses: <ol style="list-style-type: none"> 1. Turner syndrome [chart notes required] OR 2. Noonan syndrome [chart notes required] OR 3. Prader-Willi syndrome [chart notes required] OR 4. SHOX gene deficiency [chart notes required] OR 5. Short bowel syndrome (SBS) AND BOTH of the following: <ol style="list-style-type: none"> A. The patient is receiving specialized nutritional support [chart notes required] AND B. ONE of the following: 							

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	<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 OR 6. Panhypopituitarism or has deficiencies in at least THREE or more pituitary axes AND serum insulin-like growth factor-1 (IGF-1) levels below the age- and sex-appropriate reference range when off GH therapy [chart notes required] OR 7. Chronic renal insufficiency AND BOTH of the following: <ol style="list-style-type: none"> A. The patient's height velocity (HV) for age is less than -1.88 SD OR HV for age is less than the 3rd percentile [chart notes required] AND B. Other etiologies for growth impairment have been addressed OR 8. Small for gestational age (SGA) AND ALL of the following: <ol style="list-style-type: none"> A. The patient is 2 years of age or older AND B. The patient has a documented birth weight and/or birth length that is greater than or equal to 2 SD below the mean for gestational age [chart notes required] AND C. At 24 months of age, the patient failed to manifest catch-up growth evidenced by a height that remains greater than or equal to 2 SD below the mean for age and sex [chart notes required] OR 9. Idiopathic short stature (ISS) AND ALL of the following: <ol style="list-style-type: none"> A. The patient has a height less than or equal to -2.25 SD below the corresponding mean height for age and sex [chart notes required] AND B. The patient has open epiphyses AND C. ONE of the following: <ol style="list-style-type: none"> 1. The patient has a predicted adult height that is below the normal range AND ONE of the following: <ol style="list-style-type: none"> A. The patient's sex is male and predicted adult height is less than 63 inches OR B. The patient's sex is female and predicted adult height is less than 59 inches OR 2. The patient is greater than 2 SD below their mid-parental target height AND D. BOTH of the following: <ol style="list-style-type: none"> 1. The patient has been evaluated for constitutional delay of growth and puberty (CDGP) AND 2. The patient does NOT have a diagnosis of CDGP OR 10. Growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous growth hormone (GH) AND ONE of the following: <ol style="list-style-type: none"> A. The patient has extreme short stature (e.g., height less than or equal to -3 SD), normal nutrition, significantly reduced insulin-like growth factor-1 (IGF-1) and IGFBP-3 (e.g., less than -2 SD), and delayed bone age [chart notes required] OR B. BOTH of the following [chart notes required]: <ol style="list-style-type: none"> 1. The patient has ONE of the following: <ol style="list-style-type: none"> A. Height greater than 2 SD below the mean for age and sex OR B. Height greater than 1.5 SD below the mid-parental height OR C. A decrease in height SD of greater than 0.5 SD over one year in children greater than 2 years of age OR D. Height velocity (HV) greater than 2 SD below the mean over one year or greater than 1.5 SD sustained over two years OR E. Height-for-age curve that has deviated downward across two major height percentile curves (e.g., from above the 25th percentile to below the 10th percentile) OR

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	<ul style="list-style-type: none"> F. BOTH of the following: <ul style="list-style-type: none"> 1. The patient's age is 2-4 years AND 2. The patient has a HV less than 5.5 cm/year (less than 2.2 inches/year) OR G. BOTH of the following: <ul style="list-style-type: none"> 1. The patient's age is 4-6 years AND 2. The patient has a HV less than 5 cm/year (less than 2 inches/year) OR H. The patient's age is 6 years to puberty AND ONE of the following: <ul style="list-style-type: none"> 1. The patient's sex is male and HV is less than 4 cm/year (less than 1.6 inches/year) OR 2. The patient's sex is female and HV is less than 4.5 cm/year (less than 1.8 inches/year) AND <ul style="list-style-type: none"> 2. The patient has ONE of the following: <ul style="list-style-type: none"> A. Failed at least TWO GH stimulation tests (e.g., peak GH value of less than 10 mcg/L after stimulation, or otherwise considered abnormal as determined by testing lab) OR B. Failed at least ONE GH stimulation test (e.g., peak GH value of less than 10 mcg/L after stimulation, or otherwise considered abnormal as determined by testing lab) AND ONE of the following: <ul style="list-style-type: none"> 1. Pathology of the central nervous system OR 2. History of irradiation OR 3. Other pituitary hormone defects (e.g., multiple pituitary hormone deficiency [MPHD]) OR 4. A genetic defect OR C. A pituitary abnormality and a known deficit of at least ONE other pituitary hormone 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 <ul style="list-style-type: none"> 3. ONE of the following: <ul style="list-style-type: none"> A. The request is for a preferred agent OR B. The request is for a non-preferred agent AND ONE of the following: <ul 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. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR 3. The patient has tried and had an inadequate response to ONE preferred agent [chart notes required] OR 4. ONE preferred agent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR 5. The patient has an intolerance or hypersensitivity to ONE preferred agent that is NOT expected to occur with the requested agent (medical records required) OR 6. The patient has an FDA labeled contraindication to ALL preferred agent(s) that is NOT expected to occur with the requested agent (medical records required) OR 7. 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

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	<p>performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR</p> <p>8. ONE preferred agent is not in the best interest of the patient based on medical necessity [chart notes required] OR</p> <p>9. 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>10. There is support for the efficacy of the requested agent over ALL preferred agent(s) for the requested indication (medical records required) AND</p> <p>4. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>5. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., endocrinologist), or the prescriber has consulted with a specialist in the area of the patient’s diagnosis AND</p> <p>6. The requested quantity (dose) is within FDA labeling or supported in compendia for the requested indication</p> <p>Compendia Allowed: AHFS or DrugDex 1, 2a, or 2b level of evidence</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>BCBSIL and BCBSMT: 12 months</p> <p>BCBSNM: 3 months - SBS; 12 months - all other indications</p> <p>ALL other plans: 4 weeks - SBS; 12 months - all other indications</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. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following:</p> <ol style="list-style-type: none"> 1. The patient does NOT have any FDA labeled contraindications to the requested agent AND 2. The requested indication is a rare disease AND 3. 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

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	<p style="text-align: center;">2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR</p> <p>3. 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 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> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>Children – 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 therapy with growth hormone (GH) through the plan's Prior Authorization process (Note: patients not previously approved for therapy with GH will require initial evaluation review) AND 2. The patient is a child (as defined by the prescriber) AND 3. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of short bowel syndrome (SBS) AND BOTH of the following: <ol style="list-style-type: none"> 1. The patient has had clinical benefit with the requested agent AND 2. 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 OR B. The patient has a diagnosis of idiopathic short stature (ISS) AND ALL of the following: <ol style="list-style-type: none"> 1. The patient's height has increased greater than or equal to 2 cm over the previous year with GH therapy AND 2. ONE of the following: <ol style="list-style-type: none"> A. The patient's sex is male and bone age is less than 16 years OR B. The patient's sex is female and bone age is less than 15 years AND

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	<p>3. The patient has open epiphyses OR</p> <p>C. BOTH of the following:</p> <ol style="list-style-type: none"> 1. The patient has ONE of the following diagnoses: <ol style="list-style-type: none"> A. Growth hormone deficiency (GHD) or growth failure due to inadequate secretion of endogenous GH OR B. Noonan's syndrome OR C. SHOX deficiency OR D. Turner syndrome OR E. Small for gestational age (SGA) OR F. Renal function impairment with growth failure AND 2. BOTH of the following: <ol style="list-style-type: none"> A. The patient does NOT have closed epiphyses AND B. The patient's height has increased greater than or equal to 2 cm over the previous year with GH therapy OR <p>D. The patient has a diagnosis of Prader-Willi syndrome AND has had clinical benefit with the requested agent OR</p> <p>E. The patient has a diagnosis other than SBS, ISS, GHD, growth failure due to inadequate secretion of endogenous GH, Noonan's syndrome, SHOX deficiency, Turner syndrome, SGA, renal function impairment with growth failure, and Prader-Willi syndrome AND has had clinical benefit with the requested agent AND</p> <p>4. ONE of the following:</p> <ol style="list-style-type: none"> A. The request is for a preferred agent OR B. The request is for a non-preferred agent AND 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. The patient is currently being treated with the requested agent and the patient is [currently stable on the requested agent [chart notes required]] OR 3. The patient has tried and had an inadequate response to ONE preferred agent [chart notes required] OR 4. ONE preferred agent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR 5. The patient has an intolerance or hypersensitivity to ONE preferred agent that is NOT expected to occur with the requested agent (medical records required) OR 6. The patient has an FDA labeled contraindication to ALL preferred agent(s) that is NOT expected to occur with the requested agent (medical records required) OR 7. 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 8. ONE preferred agent is not in the best interest of the patient based on medical necessity [chart notes required] OR 9. 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 10. There is support for the efficacy of the requested agent over ALL preferred agent(s) for the requested indication (medical records required) AND <p>5. The patient is being monitored for adverse effects of GH AND</p> <p>6. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND</p>

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	<p data-bbox="277 180 1382 239">8. The requested quantity (dose) is within FDA labeling or supported in compendia for the requested indication</p> <p data-bbox="232 275 1089 306">Compendia Allowed: AHFS or DrugDex 1, 2a, or 2b level of evidence</p> <p data-bbox="232 342 500 373">Length of Approval:</p> <p data-bbox="232 409 483 441">BCBSOK: 36 months</p> <p data-bbox="232 476 634 508">BCBSIL and BCBSMT: 12 months</p> <p data-bbox="232 543 959 575">BCBSNM: 3 months - SBS; 12 months - all other indications</p> <p data-bbox="232 611 1024 642">ALL other plans: 4 weeks - SBS; 12 months - all other indications</p>

Criteria in this program are consistent with Health Care Service Corporation (HCSC) Medical Policy Rx501.040 Growth Hormone (GH). For additional clinical information see the Health Care Service Corporation (HCSC) Medical Policy Rx501.040 Human Growth Hormone (GH).