



# Spevigo Prior Authorization with Quantity Limit Program Summary

## POLICY REVIEW CYCLE

**Effective Date**  
11-01-2025

**Date of Origin**  
05-16-2024

## POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Spevigo	spesolimab-sbzo subcutaneous soln pref syr	150 MG/ML ; 300 MG/2ML	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
Spevigo	spesolimab-sbzo subcutaneous soln pref syr	150 MG/ML	2	Syringes	28	DAYS			
Spevigo	spesolimab-sbzo subcutaneous soln pref syr	300 MG/2ML	1	Syringe	28	DAYS			

## CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Spevigo	spesolimab-sbzo subcutaneous soln pref syr	150 MG/ML ; 300 MG/2ML	IL HMO Performance Annual ; 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 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

## CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Spevigo	spesolimab-sbzo subcutaneous soln pref syr	300 MG/2ML	IL HMO Performance Annual ; 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 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 Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Spevigo	spesolimab-sbzo subcutaneous soln pref syr	150 MG/ML	IL HMO Performance Annual ; 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 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 Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

## PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	<p><b>Initial Evaluation</b></p> <p><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> <li>1. BOTH of the following: <ol style="list-style-type: none"> <li>A. ONE of the following: <ol style="list-style-type: none"> <li>1. The patient has a diagnosis of generalized pustular psoriasis (GPP) AND ALL of the following: <ol style="list-style-type: none"> <li>A. The patient has moderate to severe GPP <b>AND</b></li> <li>B. The patient has a history of 2 or more flares <b>AND</b></li> <li>C. The patient is NOT currently experiencing an acute flare <b>OR</b></li> </ol> </li> </ol> </li> </ol> </li> </ol>

Module	Clinical Criteria for Approval
	<p style="margin-left: 40px;">2. The patient has another FDA labeled indication for the requested agent <b>AND</b></p> <p style="margin-left: 20px;">B. If the patient has an FDA labeled indication, then ONE of the following:</p> <p style="margin-left: 40px;">1. The patient’s age is within FDA labeling for the requested indication for the requested agent <b>OR</b></p> <p style="margin-left: 40px;">2. There is support for using the requested agent for the patient’s age <b>AND</b></p> <p>2. If the patient has a diagnosis of GPP, then the patient weighs greater than or equal to 40 kg <b>AND</b></p> <p>3. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., dermatologist), or the prescriber has consulted with a specialist in the area of the patient’s diagnosis <b>AND</b></p> <p>4. ONE of the following:</p> <p style="margin-left: 20px;">A. The patient does NOT have active or latent tuberculosis (TB) <b>OR</b></p> <p style="margin-left: 20px;">B. The patient has latent tuberculosis (TB) and the patient has begun or completed therapy for latent TB prior to initiating therapy with the requested agent <b>AND</b></p> <p>5. ONE of the following (Please refer to “Agents NOT to be used Concomitantly” table):</p> <p style="margin-left: 20px;">A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) <b>OR</b></p> <p style="margin-left: 20px;">B. The patient will be using the requested agent in combination with another immunomodulatory agent <b>AND BOTH</b> of the following:</p> <p style="margin-left: 40px;">1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent <b>AND</b></p> <p style="margin-left: 40px;">2. There is support for the use of combination therapy (copy of support required, i.e., clinical trials, phase III studies, guidelines) <b>AND</b></p> <p>6. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p><b>Length of Approval:</b></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><b>The requested agent will also be approved when ONE of the following is met:</b></p> <p>1. The request is for a BCBS MT Fully Insured or MT HIM member <b>AND</b></p> <p style="margin-left: 20px;">A. The patient is under the age of 18 years old <b>AND</b></p> <p style="margin-left: 20px;">B. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></p> <p style="margin-left: 20px;">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] <b>AND</b></p> <p style="margin-left: 20px;">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] <b>OR</b></p> <p>2. ALL of the following:</p> <p style="margin-left: 20px;">A. The member resides in Ohio <b>AND</b></p> <p style="margin-left: 20px;">B. The plan is Fully Insured or HIM Shop (SG) <b>AND</b></p> <p style="margin-left: 20px;">C. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></p>

Module	Clinical Criteria for Approval
	<p>D. ONE of the following:</p> <ol style="list-style-type: none"> <li>1. The patient has another FDA labeled indication for the requested agent and route of administration <b>OR</b></li> <li>2. The patient has another indication that is supported in compendia for the requested agent and route of administration <b>OR</b></li> <li>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]</li> </ol> <p><b>Non-oncology compendia allowed:</b> DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p><b>Oncology compendia allowed:</b> 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><b>Length of Approval:</b></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><b>Renewal Evaluation</b></p> <p><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> <li>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] <b>AND</b></li> <li>2. The patient has had clinical benefit with the requested agent <b>AND</b></li> <li>3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis <b>AND</b></li> <li>4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): <ol style="list-style-type: none"> <li>A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) <b>OR</b></li> <li>B. The patient will be using the requested agent in combination with another immunomodulatory agent <b>AND BOTH</b> of the following: <ol style="list-style-type: none"> <li>1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent <b>AND</b></li> <li>2. There is support for the use of combination therapy (copy of support required, i.e., clinical trials, phase III studies, guidelines) <b>AND</b></li> </ol> </li> </ol> </li> <li>5. The patient does NOT have any FDA labeled contraindications to the requested agent</li> </ol> <p><b>Length of Approval:</b></p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p>

Module	Clinical Criteria for Approval
	NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

## QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p><b>Quantity limit for the Target Agent(s)</b> will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> <li>1. The requested quantity (dose) does NOT exceed the program quantity limit <b>OR</b></li> <li>2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: <ol style="list-style-type: none"> <li>A. BOTH of the following: <ol style="list-style-type: none"> <li>1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>2. There is support for therapy with a higher dose for the requested indication <b>OR</b></li> </ol> </li> <li>B. BOTH of the following: <ol style="list-style-type: none"> <li>1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>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 <b>OR</b></li> </ol> </li> <li>C. BOTH of the following: <ol style="list-style-type: none"> <li>1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>2. There is support for therapy with a higher dose for the requested indication</li> </ol> </li> </ol> </li> </ol> <p><b>Length of Approval:</b> 12 months</p> <p><b>Note: If patient is NOT transitioning from IV to SC maintenance:</b> Approve Spevigo loading dose for 1 month, then maintenance dose can be approved for the remainder of 12 months. <b>Patient IS transitioning from IV to SC maintenance dosing due to a recent flare:</b> Approve 12 months for maintenance therapy.</p>

## CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
<p><b>Agents NOT to be used Concomitantly</b></p> <p>Abrilada (adalimumab-afzb)  Actemra (tocilizumab)  Adalimumab  Adbry (tralokinumab-ldrm)  Amjevita (adalimumab-atto)  Arcalyst (riloncept)  Avsola (infliximab-axxq)  Avtozma (tocilizumab-anoh)  Benlysta (belimumab)  Bimzelx (bimekizumab-bkzx)  Cibinqo (abrocitinib)  Cimzia (certolizumab)  Cinqair (reslizumab)  Cosentyx (secukinumab)  Cyltezo (adalimumab-adbm)  Dupixent (dupilumab)  Ebglyss (lebrikizumab-lbkz)  Enbrel (etanercept)  Entyvio (vedolizumab)  Fasenra (benralizumab)</p>

**Contraindicated as Concomitant Therapy**

Hadlima (adalimumab-bwwd)  
Hulio (adalimumab-fkjp)  
Humira (adalimumab)  
Hyrimoz (adalimumab-adaz)  
Idacio (adalimumab-aacf)  
Ilaris (canakinumab)  
Ilumya (tildrakizumab-asmn)  
Imuldosa (ustekinumab-srlf)  
Inflectra (infliximab-dyyb)  
Infliximab  
Kevzara (sarilumab)  
Kineret (anakinra)  
Leqselvi (deuruxolitinib)  
Litfulo (ritlecitinib)  
Nemluvio (nemolizumab-ilto)  
Nucala (mepolizumab)  
Olumiant (baricitinib)  
Omlyclo (omalizumab-igec)  
Omvoh (mirikizumab-mrkz)  
Opzelura (ruxolitinib)  
Orencia (abatacept)  
Otezla (apremilast)  
Otulfi (ustekinumab-aaaz)  
Pyzchiva (ustekinumab-ttwe)  
Remicade (infliximab)  
Renflexis (infliximab-abda)  
Riabni (rituximab-arrx)  
Rinvoq (upadacitinib)  
Rituxan (rituximab)  
Rituxan Hycela (rituximab/hyaluronidase human)  
Ruxience (rituximab-pvvr)  
Saphnelo (anifrolumab-fnia)  
Selarsdi (ustekinumab-aekn)  
Siliq (brodalumab)  
Simlandi (adalimumab-ryvk)  
Simponi (golimumab)  
Simponi ARIA (golimumab)  
Skyrizi (risankizumab-rzaa)  
Sotyktu (deucravacitinib)  
Spevigo (spesolimab-sbzo) subcutaneous injection  
Stelara (ustekinumab)  
Steqeyma (ustekinumab-stba)  
Taltz (ixekizumab)  
Tezspire (tezepelumab-ekko)  
Tofidence (tocilizumab-bavi)  
Tremfya (guselkumab)  
Truxima (rituximab-abbs)  
Tyenne (tocilizumab-aazg)  
Tysabri (natalizumab)  
Ustekinumab  
Velsipity (etrasimod)  
Wezlana (ustekinumab-auub)  
Xeljanz (tofacitinib)  
Xeljanz XR (tofacitinib extended release)  
Xolair (omalizumab)  
Yesintek (ustekinumab-kfce)  
Yuflyma (adalimumab-aaty)  
Yusimry (adalimumab-aqvh)  
Zeposia (ozanimod)  
Zymfentra (infliximab-dyyb)