

HCPA Biologic Immunomodulators Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
03-15-2026

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
Orencia	abatacept for iv soln	250 MG	M ; N ; O ; Y	N		
Cimzia	Certolizumab Pegol For Inj Kit 2 X 200 MG	200 MG	M ; N ; O ; Y	N		
Simponi aria	golimumab iv soln	50 MG/4ML	M ; N ; O ; Y	N		
Tremfya	guselkumab iv soln	200 MG/20ML	M ; N ; O ; Y	N		
Infliximab ; Remicade	infliximab for iv inj	100 MG	M ; N ; O ; Y	N		
Renflexis	infliximab-abda for iv inj	100 MG	M ; N ; O ; Y	N		
Avsola	infliximab-axxq for iv inj	100 MG	M ; N ; O ; Y	N		
Inflectra	infliximab-dyyb for iv inj	100 MG	M ; N ; O ; Y	N		
Omvo	mirikizumab-mrkz iv soln	300 MG/15ML	M ; N ; O ; Y	N		
Skyrizi	risankizumab-rzaa iv soln	600 MG/10ML	M ; N ; O ; Y	N		
Cosentyx	secukinumab iv soln	125 MG/5ML	M ; N ; O ; Y	N		
Ilumya	tildrakizumab-asmn subcutaneous soln pref syringe	100 MG/ML	M ; N ; O ; Y	N		
Actemra	tocilizumab iv inj	200 MG/10ML ; 400 MG/20ML ; 80 MG/4ML	M ; N ; O ; Y	N		
Tyenne	tocilizumab-aazg iv inj	200 MG/10ML ; 400 MG/20ML ; 80 MG/4ML	M ; N ; O ; Y	N		
Avtozma	tocilizumab-anoh iv inj	200 MG/10ML ; 400 MG/20ML ; 80 MG/4ML	M ; N ; O ; Y	N		
Tofidence	tocilizumab-bavi iv inj	200 MG/10ML ; 400 MG/20ML ; 80 MG/4ML	M ; N ; O ; Y	N		
Stelara ; Ustekinumab	ustekinumab iv soln	130 MG/26ML	M ; N ; O ; Y	N		
Otulfi	ustekinumab-aaaz iv soln	130 MG/26ML	M ; N ; O ; Y	N		
Selarsdi	ustekinumab-aeqn iv soln	130 MG/26ML	M ; N ; O ; Y	N		
Wezlana	ustekinumab-auub iv soln	130 MG/26ML	M ; N ; O ; Y	N		
Starjemza	ustekinumab-hmny iv soln	130 MG/26ML	M ; N ; O ; Y	N		
Yesintek	ustekinumab-kfce iv soln	130 MG/26ML	M ; N ; O ; Y	N		
Imuldosa	ustekinumab-srlf iv soln	130 MG/26ML	M ; N ; O ; Y	N		
Steqeyma	ustekinumab-stba iv soln	130 MG/26ML	M ; N ; O ; Y	N		
Pyzchiva ; Ustekinumab-ttwe	ustekinumab-ttwe iv soln	130 MG/26ML	M ; N ; O ; Y	N		
Entyvio	vedolizumab for iv solution	300 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
Avtozma	tocilizumab-anoh iv inj	80 MG/4ML	10	Vials	28	DAYS			
Avtozma	tocilizumab-anoh iv inj	200 MG/10ML	4	Vials	28	DAYS			
Avtozma	tocilizumab-anoh iv inj	400 MG/20ML	2	Vials	28	DAYS			
Cimzia	Certolizumab Pegol For Inj Kit 2 X 200 MG	200 MG	2	Kits	28	DAYS			
Cosentyx	secukinumab iv soln	125 MG/5ML	2	Vials	28	DAYS	calculation based on CDC 90 percentile for weight in adults and averaged for men and women to 247.5 lbs (112 kg)		
Entyvio	Vedolizumab For IV Solution 300 MG	300 MG	1	Vial	56	DAYS			
Ilumya	Tildrakizumab-asmn Subcutaneous Soln Pref Syringe 100 MG/ML	100 MG/ML	1	Syringe	84	DAYS			
Imuldosa	ustekinumab-srlf iv soln	130 MG/26ML	1	Vial	180	DAYS			
OmvoH	mirikizumab-mrkz iv soln	300 MG/15ML	3	Vials	180	DAYS			
Orencia	Abatacept For IV Soln 250 MG	250 MG	4	Vials	28	DAYS			
OtulfI	ustekinumab-aauz iv soln	130 MG/26ML	4	Vials	180	DAYS			
Pyzchiva ; Ustekinumab-ttwe	ustekinumab-ttwe iv soln	130 MG/26ML	4	Vials	180	DAYS			
Selarsdi	ustekinumab-aekn iv soln	130 MG/26ML	4	Vials	180	DAYS			
Starjemza	ustekinumab-hmny iv soln	130 MG/26ML	4	Vials	180	DAYS			
Steqeyma	ustekinumab-stba iv soln	130 MG/26ML	4	Vials	180	DAYS			
Tofidence	tocilizumab-bavi iv inj	80 MG/4ML	10	Vials	28	DAYS			
Tofidence	tocilizumab-bavi iv inj	200 MG/10ML	4	Vials	28	DAYS			
Tofidence	tocilizumab-bavi iv inj	400 MG/20ML	2	Vials	28	DAYS			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Tremfya	guselkumab iv soln	200 MG/20ML	3	Vials	180	DAYS			
Tyenne	tocilizumab-aazg iv inj	80 MG/4ML	10	Vials	28	DAYS			
Tyenne	tocilizumab-aazg iv inj	200 MG/10ML	4	Vials	28	DAYS			
Tyenne	tocilizumab-aazg iv inj	400 MG/20ML	4	Vials	28	DAYS			
Wezlana	ustekinumab-auub iv soln	130 MG/26ML	4	Vials	180	DAYS			
Yesintek	ustekinumab-kfce iv soln	130 MG/26ML	4	Vials	180	DAYS			
Skyrizi	Risankizumab-rzaa IV Soln	600 MG/10ML	6	Vials	180	DAYS			

ADDITIONAL QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
90250575002050	Cosentyx	secukinumab iv soln	125 MG/5ML	calculation based on CDC 90 percentile for weight in adults and averaged for men and women to 247.5 lbs (112 kg)		11-06-2023	

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Actemra	tocilizumab iv inj	200 MG/10ML ; 400 MG/20ML ; 80 MG/4ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Avsola	infliximab-axxq for iv inj	100 MG	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Avtozma	tocilizumab-anoh iv inj	200 MG/10ML ; 400 MG/20ML ; 80 MG/4ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Cimzia	Certolizumab Pegol For Inj Kit 2 X 200 MG	200 MG	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Cosentyx	secukinumab iv soln	125 MG/5ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Entyvio	vedolizumab for iv solution	300 MG	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Ilumya	tildrakizumab-asmn subcutaneous soln pref syringe	100 MG/ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Imuldosa	ustekinumab-srlf iv soln	130 MG/26ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Inflixtra	infliximab-dyyb for iv inj	100 MG	Basic ; Basic Annual ; Enhanced ; Enhanced Annual

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Infliximab ; Remicade	infliximab for iv inj	100 MG	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
OmvoH	mirikizumab-mrkz iv soln	300 MG/15ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Orencia	abatacept for iv soln	250 MG	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
OtulfI	ustekinumab-aauz iv soln	130 MG/26ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Pyzchiva ; Ustekinumab-ttwe	ustekinumab-ttwe iv soln	130 MG/26ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Renflexis	infliximab-abda for iv inj	100 MG	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Selarsdi	ustekinumab-aekn iv soln	130 MG/26ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Simponi aria	golimumab iv soln	50 MG/4ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Skyrizi	risankizumab-rzaa iv soln	600 MG/10ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Starjemza	ustekinumab-hmny iv soln	130 MG/26ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Stelara ; Ustekinumab	ustekinumab iv soln	130 MG/26ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Steqeyma	ustekinumab-stba iv soln	130 MG/26ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Tofidence	tocilizumab-bavi iv inj	200 MG/10ML ; 400 MG/20ML ; 80 MG/4ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Tremfya	guselkumab iv soln	200 MG/20ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Tyenne	tocilizumab-aazg iv inj	200 MG/10ML ; 400 MG/20ML ; 80 MG/4ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Wezlana	ustekinumab-auub iv soln	130 MG/26ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Yesintek	ustekinumab-kfce iv soln	130 MG/26ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Avtozma	tocilizumab-anoh iv inj	200 MG/10ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Avtozma	tocilizumab-anoh iv inj	400 MG/20ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Avtozma	tocilizumab-anoh iv inj	80 MG/4ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Cimzia	Certolizumab Pegol For Inj Kit 2 X 200 MG	200 MG	Basic ; Basic Annual ; Enhanced ; Enhanced Annual

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Cosentyx	secukinumab iv soln	125 MG/5ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Entyvio	Vedolizumab For IV Solution 300 MG	300 MG	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Ilumya	Tildrakizumab-asmn Subcutaneous Soln Pref Syringe 100 MG/ML	100 MG/ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Imuldosa	ustekinumab-srlf iv soln	130 MG/26ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
OmvoH	mirikizumab-mrzk iv soln	300 MG/15ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Orencia	Abatacept For IV Soln 250 MG	250 MG	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Otulfi	ustekinumab-aaaz iv soln	130 MG/26ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Pyzchiva ; Ustekinumab-ttwe	ustekinumab-ttwe iv soln	130 MG/26ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Selarsdi	ustekinumab-aeKn iv soln	130 MG/26ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Starjemza	ustekinumab-hmny iv soln	130 MG/26ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Steqeyma	ustekinumab-stba iv soln	130 MG/26ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Tofidence	tocilizumab-bavi iv inj	80 MG/4ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Tofidence	tocilizumab-bavi iv inj	400 MG/20ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Tofidence	tocilizumab-bavi iv inj	200 MG/10ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Tremfya	guselkumab iv soln	200 MG/20ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Tyenne	tocilizumab-aazg iv inj	80 MG/4ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Tyenne	tocilizumab-aazg iv inj	200 MG/10ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Tyenne	tocilizumab-aazg iv inj	400 MG/20ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Wezlana	ustekinumab-auub iv soln	130 MG/26ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Yesintek	ustekinumab-kfce iv soln	130 MG/26ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Skyrizi	Risankizumab-rzaa IV Soln	600 MG/10ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval			
1. Infliximab and Infliximab Biosimilars	Preferred Infliximab Target Agent(s)	Non-Preferred Infliximab Target Agent(s)		
	Avsola, Inflectra, Remicade, Infliximab (unbranded)	Ixifi, Renflexis		
Initial Evaluation				
Target Agents(s) will be approved when ALL of the following are met:				
1. ONE of the following: <ul style="list-style-type: none"> A. 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				
<ul 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 90 days AND is at risk if therapy is changed OR B. ONE of the following: <ul style="list-style-type: none"> 1. BOTH of the following: <ul style="list-style-type: none"> A. ONE of the following: <ul style="list-style-type: none"> 1. The patient has a diagnosis of moderately to severely active rheumatoid arthritis (RA) AND BOTH of the following: <ul style="list-style-type: none"> A. ONE of the following: <ul style="list-style-type: none"> 1. The patient has ONE of the following: <ul style="list-style-type: none"> A. Tried and had an inadequate response to maximally tolerated methotrexate (e.g., titrated to 25 mg weekly) after at least a 3-month duration of therapy OR B. Tried and had an inadequate response to ONE conventional agent (i.e., hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA after at least a 3-month duration of therapy OR C. An intolerance or hypersensitivity to ONE conventional agent (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA OR D. An FDA labeled contraindication to ALL conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA OR 2. The patient's medication history (excluding sample use) indicates use of a biologic immunomodulator agent or a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in compendia for the treatment of RA AND B. ONE of the following: <ul style="list-style-type: none"> 1. The patient will be using a conventional agent (i.e., methotrexate, hydroxychloroquine, leflunomide, 				

Module	Clinical Criteria for Approval
	<p>sulfasalazine) in combination with the requested agent OR</p> <ol style="list-style-type: none"> 2. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to ALL conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) OR <ol style="list-style-type: none"> 2. The patient has a diagnosis of active psoriatic arthritis (PsA) AND ONE of the following: <ol style="list-style-type: none"> A. The patient has ONE of the following: <ol style="list-style-type: none"> 1. Tried and had an inadequate response to ONE conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA after at least a 3-month duration of therapy OR 2. An intolerance or hypersensitivity to ONE conventional agent used in the treatment of PsA OR 3. An FDA labeled contraindication to ALL conventional agents used in the treatment of PsA OR 4. Severe active PsA (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities, vision loss], rapidly progressive) OR 5. Concomitant severe psoriasis (PS) (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) OR B. The patient's medication history (excluding sample use) indicates use of a biologic immunomodulator agent or a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in compendia for the treatment of PsA OR 3. The patient has a diagnosis of chronic severe plaque psoriasis (PS) OR 4. The patient has a diagnosis of moderately to severely active Crohn's disease (CD) AND ONE of the following: <ol style="list-style-type: none"> A. The patient has ONE of the following: <ol style="list-style-type: none"> 1. Tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., prednisone, budesonide EC capsule], methotrexate) used in the treatment of CD after at least a 3-month duration of therapy OR 2. An intolerance or hypersensitivity to ONE conventional agent used in the treatment of CD OR 3. An FDA labeled contraindication to ALL conventional agents used in the treatment of CD OR 4. Severely active Crohn's disease OR B. The patient's medication history (excluding sample use) indicates use of a biologic immunomodulator agent or a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in compendia for the treatment of CD OR

Module	Clinical Criteria for Approval
	<p>5. The patient has a diagnosis of moderately to severely active ulcerative colitis (UC) AND ONE of the following:</p> <ul style="list-style-type: none"> A. The patient has ONE of the following: <ul style="list-style-type: none"> 1. Tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC after at least a 3-month duration of therapy OR 2. An intolerance or hypersensitivity to ONE conventional agent used in the treatment of UC OR 3. An FDA labeled contraindication to ALL conventional agents used in the treatment of UC OR 4. Severely active ulcerative colitis OR B. The patient's medication history (excluding sample use) indicates use of a biologic immunomodulator agent or a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in compendia for the treatment of UC OR <p>6. The patient has a diagnosis of active ankylosing spondylitis (AS) AND ONE of the following:</p> <ul style="list-style-type: none"> A. The patient has ONE of the following: <ul style="list-style-type: none"> 1. Tried and had an inadequate response to TWO different nonsteroidal anti-inflammatory drugs (NSAIDs) used in the treatment of AS after at least a 4-week TOTAL duration of therapy OR 2. Tried and had an inadequate response to ONE NSAID used in the treatment of AS after at least a 4-week duration of therapy and an intolerance or hypersensitivity to ONE additional NSAID used in the treatment of AS OR 3. An intolerance or hypersensitivity to TWO different NSAIDs used in the treatment of AS OR 4. An FDA labeled contraindication to ALL NSAIDs used in the treatment of AS OR B. The patient's medication history (excluding sample use) indicates use of a biologic immunomodulator agent or a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in compendia for the treatment of AS OR <p>7. The patient has another FDA labeled indication for the requested agent and route of administration AND</p> <ul style="list-style-type: none"> B. If the patient has an FDA labeled indication, then ONE of the following: <ul 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 of using the requested agent for the patient's age for the requested indication OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration AND <p>2. ONE of the following (reference preferred agents table):</p> <ul style="list-style-type: none"> A. The requested agent is a preferred agent OR B. BOTH of the following: <ul style="list-style-type: none"> 1. ONE of the following: <ul style="list-style-type: none"> A. The patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer OR

Module	Clinical Criteria for Approval
	<p>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</p> <p>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</p> <p>C. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR</p> <p>D. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR</p> <p>E. The patient has tried and had an inadequate response to TWO preferred agent(s) after at least a 3-month duration of therapy per agent (medical records required) OR</p> <p>F. TWO preferred agent(s) were discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR</p> <p>G. The patient has an intolerance or hypersensitivity to TWO preferred agent(s) that is not expected to occur with the requested agent (medical records required) OR</p> <p>H. 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</p> <p>I. TWO preferred agent(s) are expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR</p> <p>J. TWO preferred agent(s) are not in the best interest of the patient based on medical necessity [chart notes required] OR</p> <p>K. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as TWO preferred agent(s) 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>3. The patient has been tested for latent tuberculosis (TB) AND if positive the patient has begun therapy for latent TB AND</p> <p>4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for PsA, RA; gastroenterologist for CD, UC; dermatologist for PS), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND</p> <p>5. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):</p> <p>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) OR</p> <p>B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:</p> <p>1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent AND</p> <p>2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required) AND</p> <p>6. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>7. ONE of the following:</p> <p>A. The requested quantity (dose) is within FDA labeled dosing (or supported in compendia) for the requested indication OR</p> <p>B. The requested quantity (dose) exceeds the maximum FDA labeled dose AND the maximum compendia supported dose for the requested indication AND ALL of the following:</p> <p>1. The patient has been titrated up to the requested dose due to ineffective symptom control at lower doses AND</p> <p>2. ONE of the following:</p> <p>A. The request is either for a dose increase or shortening of the dosing interval, NOT both OR</p> <p>B. The patient is currently treated with the requested dose AND</p>

Module	Clinical Criteria for Approval
	<p data-bbox="469 180 1281 212">3. The requested dose does NOT exceed 10 mg/kg every 4 weeks</p> <p data-bbox="232 247 1333 304">Compendia Allowed: AHFS, DrugDex 1, 2a, or 2b level of evidence, or NCCN 1, 2a, or 2b recommended use</p> <p data-bbox="232 342 498 373">Length of Approval:</p> <p data-bbox="232 409 483 436">BCBSOK: 36 months</p> <p data-bbox="232 474 628 501">BCBSIL and BCBSTX: 12 months</p> <p data-bbox="232 539 891 567">ALL other plans: 12 months for all indications EXCEPT:</p> <ul data-bbox="280 609 649 636" style="list-style-type: none"> • Crohn’s disease: 14 weeks <p data-bbox="232 737 1190 768">The requested agent will also be approved when the following are met:</p> <ol data-bbox="280 806 1404 1272" style="list-style-type: none"> 1. The member resides in Ohio AND 2. The plan is Fully Insured or HIM Shop (SG) AND BOTH of the following <ol data-bbox="375 863 1404 1272" style="list-style-type: none"> A. The patient does NOT have any FDA labeled contraindications to the requested agent AND B. ONE of the following: <ol data-bbox="472 953 1404 1272" 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 data-bbox="232 1310 1396 1367">Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p data-bbox="232 1404 1382 1491">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 data-bbox="232 1528 498 1560">Length of Approval:</p> <p data-bbox="232 1598 483 1625">BCBSOK: 36 months</p> <p data-bbox="232 1663 566 1690">ALL other plans: 12 months</p> <p data-bbox="232 1728 1075 1755">NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</p> <p data-bbox="232 1856 498 1887">Renewal Evaluation</p> <p data-bbox="232 1925 1081 1957">Target Agent(s) will be approved when ALL of the following are met:</p>

Module	Clinical Criteria for Approval
	<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 AND 3. ONE of the following (reference preferred agents table): <ol style="list-style-type: none"> A. The requested agent is a preferred agent OR B. BOTH of the following: <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> 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 request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR D. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR E. The patient has tried and had an inadequate response to TWO preferred agent(s) after at least a 3-month duration of therapy per agent (medical records required) OR F. TWO preferred agent(s) were discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR G. The patient has an intolerance or hypersensitivity to TWO preferred agent(s) that is not expected to occur with the requested agent (medical records required) OR H. 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 I. TWO preferred agent(s) are expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR J. TWO preferred agent(s) are not in the best interest of the patient based on medical necessity [chart notes required] OR K. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as TWO preferred agent(s) and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] AND 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for PsA, RA; gastroenterologist for CD, UC; dermatologist for PS) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 5. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): <ol style="list-style-type: none"> 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) OR B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: <ol style="list-style-type: none"> 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent AND 2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required) AND 6. The patient does NOT have any FDA labeled contraindications to the requested agent AND 7. ONE of the following: <ol style="list-style-type: none"> A. The requested quantity (dose) is within FDA labeled dosing (or supported in compendia) for the requested indication OR

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	<p>B. The requested quantity (dose) exceeds the maximum FDA labeled dose AND the maximum compendia supported dose for the requested indication AND ALL of the following:</p> <ol style="list-style-type: none"> 1. The patient has been titrated up to the requested dose due to ineffective symptom control at lower doses AND 2. ONE of the following: <ol style="list-style-type: none"> A. The request is either for a dose increase or shortening of the dosing interval, NOT both OR B. The patient is currently treated with the requested dose AND 3. The requested dose does NOT exceed 10 mg/kg every 4 weeks <p>Compendia Allowed: AHFS, DrugDex 1, 2a, or 2b level of evidence, or NCCN 1, 2a, or 2b recommended use</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p>		
2. All other target agents	<p>Initial Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The requested agent is eligible for continuation of therapy AND the following: <table border="1" data-bbox="235 1003 1227 1083" style="margin-left: 40px;"> <tr> <td style="text-align: center;">Agents Eligible for Continuation of Therapy</td> </tr> <tr> <td style="text-align: center;">All target agents are eligible for continuation of therapy</td> </tr> </table> <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 90 days AND is at risk if therapy is changed OR B. ALL of the following: <ol style="list-style-type: none"> 1. The patient has an FDA labeled indication or an indication that is supported in compendia for the requested agent and route of administration AND 2. ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of moderately to severely active rheumatoid arthritis (RA) AND BOTH of the following: <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient has ONE of the following: <ol style="list-style-type: none"> 1. Tried and had an inadequate response to maximally tolerated methotrexate (e.g., titrated to 25 mg weekly) after at least a 3-month duration of therapy OR 2. Tried and had an inadequate response to ONE conventional agent (i.e., hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of 	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			

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	<p>RA after at least a 3-month duration of therapy OR</p> <p>3. An intolerance or hypersensitivity to ONE conventional agent (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA OR</p> <p>4. An FDA labeled contraindication to ALL conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA OR</p> <p>B. The patient's medication history (excluding sample use) indicates use of a biologic immunomodulator agent or a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in compendia for the treatment of RA AND</p> <p>2. If the request is for Simponi ARIA, then ONE of the following:</p> <p>A. The patient will be using methotrexate in combination with the requested agent OR</p> <p>B. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to methotrexate OR</p> <p>B. The patient has a diagnosis of active psoriatic arthritis (PsA) AND ONE of the following:</p> <p>1. The patient has ONE of the following:</p> <p>A. Tried and had an inadequate response to ONE conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA after at least a 3-month duration of therapy OR</p> <p>B. An intolerance or hypersensitivity to ONE conventional agent used in the treatment of PsA OR</p> <p>C. An FDA labeled contraindication to ALL conventional agents used in the treatment of PsA OR</p> <p>D. Severe active PsA (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities, vision loss], rapidly progressive) OR</p> <p>E. Concomitant severe psoriasis (PS) (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e.,</p>

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	<p>hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) OR</p> <p>2. The patient's medication history (excluding sample use) indicates use of a biologic immunomodulator agent or a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in compendia for the treatment of PsA OR</p> <p>C. The patient has a diagnosis of moderate to severe plaque psoriasis (PS) AND ONE of the following:</p> <ol style="list-style-type: none"> 1. The patient has ONE of the following: <ol style="list-style-type: none"> A. Tried and had an inadequate response to ONE conventional agent (i.e., acitretin, calcipotriene, calcitriol, coal tar, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS after at least a 3-month duration of therapy OR B. An intolerance or hypersensitivity to ONE conventional agent used in the treatment of PS OR C. An FDA labeled contraindication to ALL conventional agents used in the treatment of PS OR D. Severe active PS (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) OR E. Concomitant severe psoriatic arthritis (PsA) (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities, vision loss], rapidly progressive) OR 2. The patient's medication history (excluding sample use) indicates use of a biologic immunomodulator agent or a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in compendia for the treatment of PS OR <p>D. The patient has a diagnosis of moderately to severely active Crohn's disease (CD) AND ONE of the following:</p> <ol style="list-style-type: none"> 1. The patient has ONE of the following: <ol style="list-style-type: none"> A. Tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., prednisone, budesonide EC capsule], methotrexate) used in the treatment of CD after at least a 3-month duration of therapy OR

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	<ul style="list-style-type: none"> B. An intolerance or hypersensitivity to ONE conventional agent used in the treatment of CD OR C. An FDA labeled contraindication to ALL conventional agents used in the treatment of CD OR D. Severely active Crohn's disease OR 2. The patient's medication history (excluding sample use) indicates use of a biologic immunomodulator agent or a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in compendia for the treatment of CD OR E. The patient has a diagnosis of moderately to severely active ulcerative colitis (UC) AND ONE of the following: <ul style="list-style-type: none"> 1. The patient has ONE of the following: <ul style="list-style-type: none"> A. Tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC after at least a 3-month duration of therapy OR B. An intolerance or hypersensitivity to ONE conventional agent used in the treatment of UC OR C. An FDA labeled contraindication to ALL conventional agents used in the treatment of UC OR D. Severely active ulcerative colitis OR 2. The patient's medication history (excluding sample use) indicates use of a biologic immunomodulator agent or a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in compendia for the treatment of UC OR F. The patient has a diagnosis of active ankylosing spondylitis (AS) AND ONE of the following: <ul style="list-style-type: none"> 1. The patient has ONE of the following: <ul style="list-style-type: none"> A. Tried and had an inadequate response to TWO different nonsteroidal anti-inflammatory drugs (NSAIDs) used in the treatment of AS after at least a 4-week TOTAL duration of therapy OR B. Tried and had an inadequate response to ONE NSAID used in the treatment of AS after at least a 4-week duration of therapy and an intolerance or hypersensitivity to ONE additional NSAID used in the treatment of AS OR C. An intolerance or hypersensitivity to TWO different NSAIDs used in the treatment of AS OR D. An FDA labeled contraindication to ALL NSAIDs used in the treatment of AS OR

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	<p>2. The patient's medication history (excluding sample use) indicates use of a biologic immunomodulator agent or a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in compendia for the treatment of AS OR</p> <p>G. The patient has a diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) AND ONE of the following:</p> <ol style="list-style-type: none"> 1. The patient has ONE of the following: <ol style="list-style-type: none"> A. Tried and had an inadequate response to TWO different nonsteroidal anti-inflammatory drugs (NSAIDs) used in the treatment of nr-axSpA after at least a 4-week TOTAL duration of therapy OR B. Tried and had an inadequate response to ONE NSAID used in the treatment of nr-axSpA after at least a 4-week duration of therapy and an intolerance or hypersensitivity to ONE additional NSAID used in the treatment of nr-axSpA OR C. An intolerance or hypersensitivity to TWO different NSAIDs used in the treatment of nr-axSpA OR D. An FDA labeled contraindication to ALL NSAIDs used in the treatment of nr-axSpA OR 2. The patient's medication history (excluding sample use) indicates use of a biologic immunomodulator agent or a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in compendia for the treatment of nr-axSpA OR <p>H. The patient has a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) AND ONE of the following:</p> <ol style="list-style-type: none"> 1. The patient has ONE of the following: <ol style="list-style-type: none"> A. Tried and had an inadequate response to ONE conventional agent (i.e., methotrexate, leflunomide) used in the treatment of PJIA after at least a 3-month duration of therapy OR B. An intolerance or hypersensitivity to ONE conventional agent used in the treatment of PJIA OR C. An FDA labeled contraindication to ALL conventional agents used in the treatment of PJIA OR 2. The patient's medication history (excluding sample use) indicates use of a biologic immunomodulator agent or a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in compendia for the treatment of PJIA OR <p>I. The patient has a diagnosis of giant cell arteritis (GCA) AND ONE of the following:</p> <ol style="list-style-type: none"> 1. The patient has ONE of the following: <ol style="list-style-type: none"> A. Tried and had an inadequate response to ONE systemic corticosteroid (e.g., prednisone,

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	<p style="text-align: right;">methylprednisolone) used in the treatment of GCA after at least a 7-day duration of therapy OR</p> <p style="text-align: right;">B. An intolerance or hypersensitivity to ONE systemic corticosteroid used in the treatment of GCA OR</p> <p style="text-align: right;">C. An FDA labeled contraindication to ALL systemic corticosteroids used in the treatment of GCA OR</p> <p style="text-align: right;">2. The patient's medication history (excluding sample use) indicates use of a biologic immunomodulator agent or a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in compendia for the treatment of GCA OR</p> <p style="text-align: right;">J. The patient has another FDA labeled indication for the requested agent and route of administration AND</p> <p style="text-align: right;">2. If the patient has an FDA labeled indication, then ONE of the following:</p> <p style="text-align: right;">A. The patient's age is within FDA labeling for the requested indication for the requested agent OR</p> <p style="text-align: right;">B. There is support for using the requested agent for the patient's age for the requested indication OR</p> <p style="text-align: right;">B. The patient has another indication that is supported in compendia for the requested agent and route of administration AND</p> <p style="text-align: right;">2. If the request is for Cosentyx vial, then ONE of the following:</p> <table border="1" data-bbox="235 1003 1227 1297" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th data-bbox="235 1003 732 1037">Requested Agent</th> <th data-bbox="732 1003 1227 1037">Self-Administered Trial Agent(s)</th> </tr> </thead> <tbody> <tr> <td data-bbox="235 1037 732 1297" style="vertical-align: top;">Cosentyx 125 mg/5 mL vial</td> <td data-bbox="732 1037 1227 1297" style="vertical-align: top;"> Cosentyx Sensoready pen 150 mg/mL (1 or 2 pen dose) Cosentyx UnoReady pen 300 mg/2 mL Cosentyx prefilled syringe 75 mg/0.5 mL Cosentyx prefilled syringe 150 mg/mL (1 or 2 syringe dose) Cosentyx prefilled syringe 300 mg/2 mL </td> </tr> </tbody> </table> <p style="text-align: right;">A. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR</p> <p style="text-align: right;">B. The patient has tried a self-administered Cosentyx agent OR</p> <p style="text-align: right;">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</p> <p style="text-align: right;">D. The patient has tried and had an inadequate response to ONE self-administered Cosentyx agent [chart notes required] OR</p> <p style="text-align: right;">E. ONE self-administered Cosentyx agent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR</p> <p style="text-align: right;">F. The patient has an intolerance or hypersensitivity to ONE self-administered Cosentyx agent (that is not expected to occur with the requested agent) [chart notes required] OR</p> <p style="text-align: right;">G. The patient has an FDA labeled contraindication to ALL self-administered Cosentyx agents (that is not expected to occur with the requested agent) [chart notes required] OR</p> <p style="text-align: right;">H. ONE self-administered Cosentyx 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 style="text-align: right;">I. ONE self-administered Cosentyx agent is not in the best interest of the patient based on medical necessity [chart notes required] OR</p>	Requested Agent	Self-Administered Trial Agent(s)	Cosentyx 125 mg/5 mL vial	Cosentyx Sensoready pen 150 mg/mL (1 or 2 pen dose) Cosentyx UnoReady pen 300 mg/2 mL Cosentyx prefilled syringe 75 mg/0.5 mL Cosentyx prefilled syringe 150 mg/mL (1 or 2 syringe dose) Cosentyx prefilled syringe 300 mg/2 mL
Requested Agent	Self-Administered Trial Agent(s)				
Cosentyx 125 mg/5 mL vial	Cosentyx Sensoready pen 150 mg/mL (1 or 2 pen dose) Cosentyx UnoReady pen 300 mg/2 mL Cosentyx prefilled syringe 75 mg/0.5 mL Cosentyx prefilled syringe 150 mg/mL (1 or 2 syringe dose) Cosentyx prefilled syringe 300 mg/2 mL				

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	<p>J. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ONE self-administered Cosentyx 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 provider-administered product over the self-administered products AND</p> <p>3. ONE of the following:</p> <ol style="list-style-type: none"> 1. The prescribing information for the requested agent requires testing for latent tuberculosis (TB) AND the patient has been tested for latent TB AND if positive the patient has begun therapy for latent TB OR 2. The prescribing information for the requested agent does NOT require testing for latent tuberculosis (TB) AND <p>4. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., rheumatologist for PsA, RA; gastroenterologist for CD, UC; dermatologist for PS; oncologist for CRS), or the prescriber has consulted with a specialist in the area of the patient’s diagnosis AND</p> <p>5. ONE of the following (Please refer to “Agents NOT to be used Concomitantly” table):</p> <ol style="list-style-type: none"> 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) OR B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: <ol style="list-style-type: none"> 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent AND 2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required) AND <p>6. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Compendia Allowed: AHFS, DrugDex 1, 2a, or 2b level of evidence, or NCCN 1 or 2a recommended use</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>BCBSIL and BCBSTX: 12 months</p> <p>BCBSNM: 12 months for all agents EXCEPT:</p> <ul style="list-style-type: none"> • Tocilizumab product for CRS: one-time approval for up to 4 doses in 1 month for 3 months • Entyvio for Crohn’s disease or ulcerative colitis: 14 weeks • Omvoh for Crohn's disease or ulcerative colitis: 12 weeks • Skyrizi for Crohn's disease or ulcerative colitis: 12 weeks • Ustekinumab product for Crohn’s disease or ulcerative colitis: one-time approval for induction dose for 3 months • Tremfya for ulcerative colitis: 12 weeks <p>ALL other plans: 12 months for all agents EXCEPT</p> <ul style="list-style-type: none"> • Tocilizumab product for CRS: one-time approval for up to 4 doses in 1 month • Entyvio for Crohn’s disease or ulcerative colitis: 14 weeks • Omvoh for Crohn's disease or ulcerative colitis: 12 weeks • Skyrizi for Crohn's disease or ulcerative colitis: 12 weeks • Ustekinumab product for Crohn’s disease or ulcerative colitis: one-time approval for induction dose • Tremfya for ulcerative colitis: 12 weeks <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>

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	<p>The requested agent will also be approved when the following are met:</p> <ol style="list-style-type: none"> 1. The member resides in Ohio AND 2. The plan is Fully Insured or HIM Shop (SG) AND BOTH of the following <ol style="list-style-type: none"> A. The patient does NOT have any FDA labeled contraindications to the requested agent AND B. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p>Oncology compendia allowed: NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months</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: tocilizumab for CRS, Omvoh for CD or UC, ustekinumab for CD or UC, Skyrizi for CD or UC, and Tremfya for UC should always be reviewed under initial criteria) (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 AND 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for PsA, RA; gastroenterologist for CD, UC; dermatologist for PS; oncologist for CRS), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): <ol style="list-style-type: none"> 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) OR B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: <ol style="list-style-type: none"> 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent AND

Module	Clinical Criteria for Approval				
	<p data-bbox="277 180 1382 268">2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required) AND 5. If the request is for Cosentyx vial, then ONE of the following:</p> <table border="1" data-bbox="235 306 1227 600"> <thead> <tr> <th data-bbox="235 306 732 340">Requested Agent</th> <th data-bbox="732 306 1227 340">Self-Administered Trial Agent(s)</th> </tr> </thead> <tbody> <tr> <td data-bbox="235 340 732 600">Cosentyx 125 mg/5 mL vial</td> <td data-bbox="732 340 1227 600"> Cosentyx Sensoready pen 150 mg/mL (1 or 2 pen dose) Cosentyx UnoReady pen 300 mg/2 mL Cosentyx prefilled syringe 75 mg/0.5 mL Cosentyx prefilled syringe 150 mg/mL (1 or 2 syringe dose) Cosentyx prefilled syringe 300 mg/2 mL </td> </tr> </tbody> </table> <p data-bbox="277 642 1414 1577"> 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 has tried a self-administered Cosentyx agent 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 self-administered Cosentyx agent [chart notes required] OR E. ONE self-administered Cosentyx 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 self-administered Cosentyx agent (that is not expected to occur with the requested agent) [chart notes required] OR G. The patient has an FDA labeled contraindication to ALL self-administered Cosentyx agents (that is not expected to occur with the requested agent) [chart notes required] OR H. ONE self-administered Cosentyx 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 self-administered Cosentyx 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 self-administered Cosentyx agent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR K. There is support for the use of the requested provider-administered product over the self-administered products AND 6. The patient does NOT have any FDA labeled contraindications to the requested agent </p> <p data-bbox="228 1612 500 1646">Length of Approval:</p> <p data-bbox="228 1677 483 1711">BCBSOK: 36 months</p> <p data-bbox="228 1745 570 1778">ALL other plans: 12 months</p> <p data-bbox="228 1812 1089 1845">NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>	Requested Agent	Self-Administered Trial Agent(s)	Cosentyx 125 mg/5 mL vial	Cosentyx Sensoready pen 150 mg/mL (1 or 2 pen dose) Cosentyx UnoReady pen 300 mg/2 mL Cosentyx prefilled syringe 75 mg/0.5 mL Cosentyx prefilled syringe 150 mg/mL (1 or 2 syringe dose) Cosentyx prefilled syringe 300 mg/2 mL
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QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
All other target agent(s)	<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. The patient has an FDA labeled indication for the requested agent, AND ONE of the following: <ol style="list-style-type: none"> 1. BOTH of the following: <ol style="list-style-type: none"> A. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication AND B. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does NOT exceed the program quantity limit OR 2. ALL of the following: <ol style="list-style-type: none"> A. The requested quantity (dose) exceeds the FDA maximum labeled dose for the requested indication AND B. The patient has tried and had an inadequate response to at least a 3-month duration of therapy at the maximum FDA labeled dose for the requested indication (medical records required) AND C. ONE of the following: <ol style="list-style-type: none"> 1. BOTH of the following: <ol style="list-style-type: none"> A. The requested quantity (dose) does NOT exceed the maximum compendia supported dose for the requested indication AND B. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit OR 2. BOTH of the following: <ol style="list-style-type: none"> A. The requested quantity (dose) exceeds the maximum FDA labeled dose AND the maximum compendia supported dose for the requested indication AND B. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, or guidelines required) OR B. The patient has a compendia supported indication for the requested agent, AND ONE of the following: <ol style="list-style-type: none"> 1. BOTH of the following: <ol style="list-style-type: none"> A. The requested quantity (dose) does NOT exceed the maximum compendia supported dose for the requested indication AND B. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit OR 2. BOTH of the following: <ol style="list-style-type: none"> A. The requested quantity (dose) exceeds the maximum compendia supported dose for the requested indication AND B. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, or guidelines required) OR C. The patient does NOT have an FDA labeled indication NOR a compendia supported indication for the requested agent AND BOTH of the following: <ol style="list-style-type: none"> 1. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit AND 2. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, or guidelines required)

Module	Clinical Criteria for Approval
	<p>Compendia Allowed: AHFS, DrugDex 1, 2a, or 2b level of evidence, or NCCN 1, 2a, or 2b recommended use</p> <p>Length of Approval:</p> <p>BCBSIL: 12 months</p> <p>ALL other plans:</p> <p>INITIAL 12 months for all agents EXCEPT:</p> <ul style="list-style-type: none"> • Tocilizumab for CRS: one-time approval for up to 4 doses in 1 month • Entyvio for Crohn's disease or ulcerative colitis: 14 weeks • Omvoh for Crohn's disease or ulcerative colitis: 12 weeks • Skyrizi for Crohn's disease or ulcerative colitis: 12 weeks • Ustekinumab for Crohn's disease or ulcerative colitis: one-time approval for induction dose • Tremfya for ulcerative colitis: 12 weeks <p><u>Note:</u> For agents that require a loading dose for a new start, approve the loading dose based on FDA labeling, followed by the maintenance dose for the remainder of the length of approval</p> <p>RENEWAL: 12 months</p>

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
<p>Agents NOT to be used Concomitantly</p> <p>Abrilada (adalimumab-afzb) Actemra (tocilizumab) Adalimumab Adbry (tralokinumab-ldrm) Amjevita (adalimumab-atto) Arcalyst (rilonacept) 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) Hadlima (adalimumab-bwwd) Hulio (adalimumab-fkjp) Humira (adalimumab) Hyrimoz (adalimumab-adaz) Idacio (adalimumab-aacf) Ilaris (canakinumab)</p>

Contraindicated as Concomitant Therapy

Ilumya (tildrakizumab-asmn)
Imuldosa (ustekinumab-srlf)
Inflextra (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)
Otezla XR (apremilast extended-release)
Otulfi (ustekinumab-aaaz)
Pyzchiva (ustekinumab-ttwe)
Remicade (infliximab)
Renflexis (infliximab-abda)
Rhapsido (remibrutinib)
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
Starjemza (ustekinumab-hmny)
Stelara (ustekinumab)
Steqeyma (ustekinumab-stba)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tofidence (tocilizumab-bavi)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tyenne (tocilizumab-aazg)
Tyruko (natalizumab-sztn)
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)