



Interstitial Lung Disease Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
04-01-2026

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
Jascayd	nerandomilast tab	18 MG ; 9 MG	M ; N ; O ; Y	N		
Ofev	nintedanib esylate cap	100 MG ; 150 MG	M ; N ; O ; Y	N		
Esbriet ; Pirfenidone	pirfenidone cap ; pirfenidone tab	267 MG ; 534 MG ; 801 MG	M ; N ; O ; Y	N ; O ; Y		

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
Esbriet	Pirfenidone Cap 267 MG	267 MG	180	Capsules	30	DAYS			
Esbriet	Pirfenidone Tab 267 MG	267 MG	180	Tablets	30	DAYS			
Esbriet	Pirfenidone Tab 801 MG	801 MG	90	Tablets	30	DAYS			
Jascayd	nerandomilast tab	9 MG	60	Tablets	30	DAYS			
Jascayd	nerandomilast tab	18 MG	60	Tablets	30	DAYS			
Ofev	nintedanib esylate cap	100 MG ; 150 MG	60	Capsules	30	DAYS			
Pirfenidone	Pirfenidone Tab 534MG	534 MG	21	Tablets	180	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Esbriet ; Pirfenidone	pirfenidone cap ; pirfenidone tab	267 MG ; 534 MG ; 801 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			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
Jascayd	nerandomilast tab	18 MG ; 9 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Ofev	nintedanib esylate cap	100 MG ; 150 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; 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
Esbriet	Pirfenidone Cap 267 MG	267 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select

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
Esbriet	Pirfenidone Tab 267 MG	267 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Esbriet	Pirfenidone Tab 801 MG	801 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Jascayd	nerandomilast tab	9 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Jascayd	nerandomilast tab	18 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Ofev	nintedanib esylate cap	100 MG ; 150 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Pirfenidone	Pirfenidone Tab 534MG	534 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval				
Esbriet (pirfenidone)	<table border="1" data-bbox="235 220 1227 296"> <thead> <tr> <th data-bbox="235 220 732 258">Brand</th> <th data-bbox="732 220 1227 258">Generic Equivalent</th> </tr> </thead> <tbody> <tr> <td data-bbox="235 258 732 296">Esbriet</td> <td data-bbox="732 258 1227 296">pirfenidone</td> </tr> </tbody> </table> <p data-bbox="235 331 464 363">Initial Evaluation</p> <p data-bbox="235 401 1081 432">Target Agent(s) will be approved when ALL of the following are met:</p> <ol data-bbox="280 470 1417 1944" style="list-style-type: none"> <li data-bbox="280 470 1417 1766">ONE of the following: <ol data-bbox="375 499 1417 1766" style="list-style-type: none"> <li data-bbox="375 499 1417 814">The patient has a diagnosis of idiopathic pulmonary fibrosis (IPF) AND BOTH of the following: <ol style="list-style-type: none"> <li data-bbox="472 558 1417 642">Other known causes of interstitial lung disease (ILD) have been excluded (e.g., domestic and occupational environmental exposures, connective tissue diseases, drug toxicities, alternative diagnoses) AND <li data-bbox="472 642 1417 814">The patient has ONE of the following: <ol data-bbox="570 674 1417 814" style="list-style-type: none"> <li data-bbox="570 674 1417 726">High-resolution computed tomography (HRCT) scan with results showing a pattern for usual interstitial pneumonia (UIP) OR <li data-bbox="570 726 1417 758">Surgical lung biopsy with pathology confirming UIP OR <li data-bbox="570 758 1417 814">HRCT scan with results showing a pattern for probable UIP AND surgical lung biopsy with pathology indicating probable UIP OR <li data-bbox="375 814 1417 867">The patient has another FDA labeled indication for the requested agent and route of administration AND <li data-bbox="280 867 1417 1766">If the request is for one of the following brand agents with an available generic equivalent, then ONE of the following: <ol data-bbox="375 930 1417 1766" style="list-style-type: none"> <li data-bbox="375 930 1417 982">The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR <li data-bbox="375 982 1417 1035">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 <li data-bbox="375 1035 1417 1087">The patient has tried and had an inadequate response with the generic equivalent [chart notes are required] OR <li data-bbox="375 1087 1417 1182">The patient has an intolerance or hypersensitivity to the generic equivalent that is NOT expected to occur with the requested brand agent [chart notes are required] OR <li data-bbox="375 1182 1417 1276">The patient has an FDA labeled contraindication to the generic equivalent that is NOT expected to occur with the requested brand agent [chart notes are required] OR <li data-bbox="375 1276 1417 1329">The generic equivalent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR <li data-bbox="375 1329 1417 1539">The generic equivalent is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes are required] OR <li data-bbox="375 1539 1417 1591">The generic equivalent is NOT in the best interest of the patient based on medical necessity [chart notes are required] OR <li data-bbox="375 1591 1417 1707">The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as the generic equivalent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR <li data-bbox="375 1707 1417 1766">There is support for the use of the requested brand agent over the generic equivalent AND <li data-bbox="280 1766 1417 1860">The prescriber is a specialist in the area of the patient's diagnosis (e.g., pathologist, pulmonologist, radiologist, rheumatologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND <li data-bbox="280 1860 1417 1913">The patient will NOT be using the requested agent in combination with another target agent (Ofev) for the requested indication AND <li data-bbox="280 1913 1417 1944">The patient does NOT have any FDA labeled contraindications to the requested agent 	Brand	Generic Equivalent	Esbriet	pirfenidone
Brand	Generic Equivalent				
Esbriet	pirfenidone				

Module	Clinical Criteria for Approval
	<p>Length of Approval:</p> <p>BCBSOK: 36 months All other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>The requested agent will also be approved when ALL 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 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"> A. The patient has another FDA labeled indication for the requested agent and route of administration OR B. The patient has another indication that is supported in compendia for the requested agent and route of administration OR C. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p>Oncology compendia allowed: NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months All other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</p> <p>Renewal Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (Note: patients not previously approved for the requested agent will require initial evaluation review) AND 2. The patient has had clinical benefit with the requested agent AND 3. If the request is for one of the following brand agents with an available generic equivalent, then 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 with the generic equivalent [chart notes are required] OR

Module	Clinical Criteria for Approval
	<p>D. The patient has an intolerance or hypersensitivity to the generic equivalent that is NOT expected to occur with the requested brand agent [chart notes are required] OR</p> <p>E. The patient has an FDA labeled contraindication to the generic equivalent that is NOT expected to occur with the requested brand agent [chart notes are required] OR</p> <p>F. The generic equivalent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR</p> <p>G. The generic equivalent is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient’s adherence of care; OR worsen a comorbid condition; OR decrease the patient’s ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes are required] OR</p> <p>H. The generic equivalent is NOT in the best interest of the patient based on medical necessity [chart notes are required] OR</p> <p>I. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as the generic equivalent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR</p> <p>J. There is support for the use of the requested brand agent over the generic equivalent AND</p> <p>4. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., pathologist, pulmonologist, radiologist, rheumatologist), or the prescriber has consulted with a specialist in the area of the patient’s diagnosis AND</p> <p>5. The patient will NOT be using the requested agent in combination with another target agent (Ofev) for the requested indication AND</p> <p>6. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months All other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>
Jascayd (nerando milast)	<p>Initial Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of idiopathic pulmonary fibrosis (IPF) AND BOTH of the following: <ol style="list-style-type: none"> 1. Other known causes of interstitial lung disease (ILD) have been excluded (e.g., domestic and occupational environmental exposures, connective tissue diseases, drug toxicities, alternative diagnoses) AND 2. The patient has ONE of the following: <ol style="list-style-type: none"> A. High-resolution computed tomography (HRCT) scan with results showing a pattern for usual interstitial pneumonia (UIP) OR B. Surgical lung biopsy with pathology confirming UIP OR C. HRCT scan with results showing a pattern for probable UIP AND surgical lung biopsy with pathology indicating probable UIP OR B. The patient has another FDA labeled indication for the requested agent and route of administration AND 2. If the patient has an FDA labeled indication, then ONE of the following: <ol style="list-style-type: none"> A. The patient’s age is within FDA labeling for the requested indication for the requested agent OR B. There is support for using the requested agent for the patient’s age for the requested indication AND

Module	Clinical Criteria for Approval
	<p>3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., pathologist, pulmonologist, radiologist, rheumatologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND</p> <p>4. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months All other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>The requested agent will also be approved when ALL 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 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"> A. The patient has another FDA labeled indication for the requested agent and route of administration OR B. The patient has another indication that is supported in compendia for the requested agent and route of administration OR C. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p>Oncology compendia allowed: NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months All other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</p> <p>Renewal Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (Note: patients not previously approved for the requested agent will require initial evaluation review) AND 2. The patient has had clinical benefit with the requested agent AND

Module	Clinical Criteria for Approval
	<p>3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., pathologist, pulmonologist, radiologist, rheumatologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND</p> <p>4. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months All other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>
Ofev (nintedanib)	<p>Initial Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of idiopathic pulmonary fibrosis (IPF) AND BOTH of the following: <ol style="list-style-type: none"> 1. Other known causes of interstitial lung disease (ILD) have been excluded (e.g., domestic and occupational environmental exposures, connective tissue diseases, drug toxicities, alternative diagnoses) AND 2. The patient has ONE of the following: <ol style="list-style-type: none"> A. High-resolution computed tomography (HRCT) scan with results showing a pattern for usual interstitial pneumonia (UIP) OR B. Surgical lung biopsy with pathology confirming UIP OR C. HRCT scan with results showing a pattern for probable UIP AND surgical lung biopsy with pathology indicating probable UIP OR B. The patient has a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) AND BOTH of the following: <ol style="list-style-type: none"> 1. Diagnosis has been confirmed on high-resolution computed tomography (HRCT) or chest radiography scans AND 2. The patient has ONE of the following: <ol style="list-style-type: none"> A. Tried and had an inadequate response to ONE prerequisite agent (e.g., mycophenolate mofetil, cyclophosphamide, azathioprine) OR B. An intolerance or hypersensitivity to ONE prerequisite agent OR C. An FDA labeled contraindication to ALL prerequisite agents OR C. The patient has a diagnosis of chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype AND BOTH of the following: <ol style="list-style-type: none"> 1. The patient has TWO of the following occurring within the past year: <ol style="list-style-type: none"> A. Worsening respiratory symptoms OR B. Physiological evidence of disease progression OR C. Radiological evidence of disease progression AND 2. Alternative explanations of worsening features have been excluded OR D. The patient has another FDA labeled indication for the requested agent and route of administration AND 2. If the patient has an FDA labeled indication, then ONE of the following: <ol style="list-style-type: none"> A. The patient's age is within FDA labeling for the requested indication for the requested agent OR B. There is support for using the requested agent for the patient's age for the requested indication AND 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., pathologist, pulmonologist, radiologist, rheumatologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 4. The patient will NOT be using the requested agent in combination with another target agent (Esbriet, pirfenidone) for the requested indication AND 5. The patient does NOT have any FDA labeled contraindications to the requested agent

Module	Clinical Criteria for Approval
	<p>Length of Approval:</p> <p>BCBSOK: 36 months All other plans 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>The requested agent will also be approved when ALL 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 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"> A. The patient has another FDA labeled indication for the requested agent and route of administration OR B. The patient has another indication that is supported in compendia for the requested agent and route of administration OR C. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p>Oncology compendia allowed: NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months All other plans 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</p> <p>Renewal Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (Note: patients not previously approved for the requested agent will require initial evaluation review) AND 2. 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., pathologist, pulmonologist, radiologist, rheumatologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 4. The patient will NOT be using the requested agent in combination with another target agent (Esbriet, pirfenidone) for the requested indication AND 5. The patient does NOT have any FDA labeled contraindications to the requested agent

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	<p>Length of Approval:</p> <p>BCBSOK: 36 months All other plans 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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