



Onychomycosis Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
01-01-2026

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
Sporanox		100 MG	M ; N ; O	O ; Y		
Sporanox		10 MG/ML	M ; N ; O	O ; Y		
	ciclopirox solution	8 %	M ; N ; O ; Y	Y		
Jublia	efinaconazole soln	10 %	M ; N ; O ; Y	N		
Kerydin	tavaborole soln	5 %	M ; N ; O ; Y	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
	Ciclopirox Solution 8%	8 %	6.6	mLs	30	DAYS			
Jublia	Efinaconazole Soln 10%	10 %	4	mLs	30	DAYS			
Kerydin	Tavaborole Soln 5%	5 %	4	mLs	30	DAYS			
Sporanox	Itraconazole Cap 100 MG	100 MG	120	Capsules	30	DAYS			
Sporanox	Itraconazole Oral Soln 10 MG/ML	10 MG/ML	1200	mLs	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
	ciclopirox solution	8 %	IL HMO Performance Annual ; 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 ;

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			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 ; TX HIM Annual 2025 ; TX HIM Annual 2026
Jublia	efinaconazole soln	10 %	IL HMO Performance Annual ; 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 ; TX HIM Annual 2025 ; TX HIM Annual 2026
Kerydin	tavaborole soln	5 %	IL HMO Performance Annual ; 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 ; TX HIM Annual 2025 ; TX HIM Annual 2026
Sporanox		10 MG/ML	IL HMO Performance Annual ; 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 ; TX HIM Annual 2025 ; TX HIM Annual 2026

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Sporanox		100 MG	IL HMO Performance Annual ; 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 ; TX HIM Annual 2025 ; TX HIM Annual 2026

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
	Ciclopirox Solution 8%	8 %	IL HMO Performance Annual ; 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 ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Jublia	Efinaconazole Soln 10%	10 %	IL HMO Performance Annual ; 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 ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Kerydin	Tavaborole Soln 5%	5 %	IL HMO Performance Annual ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			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 ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Sporanox	Itraconazole Cap 100 MG	100 MG	IL HMO Performance Annual ; 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 ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Sporanox	Itraconazole Oral Soln 10 MG/ML	10 MG/ML	IL HMO Performance Annual ; 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 ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
ciclopiro x, efinacon azole,	<p>Jublia (efinaconazole), Kerydin (tavaborole), or ciclopirox will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> ONE of the following:

Module	Clinical Criteria for Approval				
tavaborole	<p data-bbox="354 180 1403 642"> A. The patient has a diagnosis of onychomycosis (tinea unguium) AND ALL of the following: <ol style="list-style-type: none"> <li data-bbox="472 239 1386 443">1. The diagnosis has been confirmed by ONE of the following lab tests [lab results required]: <ol style="list-style-type: none"> <li data-bbox="566 296 1143 325">A. Potassium hydroxide (KOH) preparation OR <li data-bbox="566 327 743 357">B. Biopsy OR <li data-bbox="566 359 834 388">C. Fungal culture OR <li data-bbox="566 390 1070 420">D. Periodic acid-Schiff (PAS) staining OR <li data-bbox="566 422 1166 451">E. Polymerase chain reaction (PCR) testing AND <li data-bbox="472 445 1403 499">2. Treatment of the patient's onychomycosis is medically necessary and not entirely for cosmetic reasons AND <li data-bbox="472 501 1382 590">3. If the requested agent is ciclopirox 8% topical solution, then treatment will include removal of the unattached, infected nail(s) by a health care professional AND <li data-bbox="472 592 1377 642">4. If the request is for one of the following brand agents, then ONE of the following: <table border="1" data-bbox="233 680 1227 846" style="margin-left: 40px;"> <thead> <tr> <th data-bbox="396 699 570 728">Brand Agent</th> <th data-bbox="743 688 1214 747">Generic antifungal onychomycosis agent</th> </tr> </thead> <tbody> <tr> <td data-bbox="237 753 334 812">Jublia, Kerydin</td> <td data-bbox="732 753 992 842">ciclopirox, itraconazole capsule, terbinafine</td> </tr> </tbody> </table> </p> <p data-bbox="566 884 1417 1980"> <ol style="list-style-type: none"> <li data-bbox="566 884 1403 938">A. 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="566 940 1395 1029">B. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR <li data-bbox="566 1031 1292 1085">C. A medication history of use within the past 90 days with ONE generic antifungal onychomycosis agent OR <li data-bbox="566 1087 1313 1176">D. The patient has tried and had an inadequate response to ONE generic antifungal onychomycosis agent [chart notes required] OR <li data-bbox="566 1178 1395 1266">E. ONE generic antifungal onychomycosis agent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR <li data-bbox="566 1268 1403 1323">F. The patient has an intolerance or hypersensitivity to ONE generic antifungal onychomycosis agent [chart notes required] OR <li data-bbox="566 1325 1370 1379">G. The patient has an FDA labeled contraindication to ALL generic antifungal onychomycosis agents [chart notes required] OR <li data-bbox="566 1381 1411 1608">H. ONE generic antifungal onychomycosis 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 <li data-bbox="566 1610 1386 1698">I. ONE generic antifungal onychomycosis agent is not in the best interest of the patient based on medical necessity [chart notes required] OR <li data-bbox="566 1701 1377 1869">J. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ONE generic antifungal onychomycosis agent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR <li data-bbox="354 1871 1352 1925">B. The patient has another FDA labeled indication for the requested agent and route of administration OR <li data-bbox="354 1927 1370 1980">C. The patient has an indication that is supported in compendia for the requested agent and route of administration AND </p>	Brand Agent	Generic antifungal onychomycosis agent	Jublia, Kerydin	ciclopirox, itraconazole capsule, terbinafine
Brand Agent	Generic antifungal onychomycosis agent				
Jublia, Kerydin	ciclopirox, itraconazole capsule, terbinafine				

Module	Clinical Criteria for Approval
	<p>2. The patient has ONE of the following:</p> <ul style="list-style-type: none"> A. Tried and had an inadequate response to ONE oral antifungal agent (itraconazole, terbinafine) OR B. An intolerance or hypersensitivity to ONE oral antifungal agent OR C. An FDA labeled contraindication to ALL oral antifungal agents OR D. The oral antifungal agents are not clinically appropriate AND <p>3. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Compendia Allowed: AHFS or DrugDex 1, 2a, or 2b level of evidence</p> <p>Length of approval:</p> <p>BCBSOK: 36 months</p> <p>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 ONE of the following is met:</p> <ul style="list-style-type: none"> 1. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following: <ul style="list-style-type: none"> A. The patient does NOT have any FDA labeled contraindications to the requested agent AND B. The requested indication is a rare disease AND C. ONE of the following: <ul 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 2. ALL of the following: <ul style="list-style-type: none"> A. The member resides in Ohio AND B. The plan is Fully Insured or HIM Shop (SG) AND C. The patient does NOT have any FDA labeled contraindications to the requested agent AND D. ONE of the following: <ul style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p>Oncology compendia allowed: NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p>Length of Approval:</p>

Module	Clinical Criteria for Approval
	<p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>
Itraconazole	<p>Sporanox (itraconazole) 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 onychomycosis (tinea unguium) AND ALL of the following: <ol style="list-style-type: none"> 1. The requested agent is Sporanox (itraconazole) capsules AND 2. The patient has not received treatment for onychomycosis with the requested agent within the past 12 months AND 3. The diagnosis has been confirmed by ONE of the following lab tests [lab results required]: <ol style="list-style-type: none"> A. Potassium hydroxide (KOH) preparation OR B. Biopsy OR C. Fungal culture OR D. Periodic acid-Schiff (PAS) staining OR E. Polymerase chain reaction (PCR) testing AND 4. Treatment of the patient's onychomycosis is medically necessary and not entirely for cosmetic reasons OR B. The patient has a diagnosis of aspergillosis AND BOTH of the following: <ol style="list-style-type: none"> 1. The requested agent is Sporanox (itraconazole) capsules 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 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 B. The patient has ONE of the following: <ol style="list-style-type: none"> A. Tried and had an inadequate response to amphotericin B OR B. An intolerance or hypersensitivity to amphotericin B OR C. An FDA labeled contraindication to amphotericin B OR C. BOTH of the following: <ol style="list-style-type: none"> 1. The patient has a diagnosis of ONE of the following: <ol style="list-style-type: none"> A. Blastomycosis OR B. Histoplasmosis OR C. Disseminated, non-meningeal histoplasmosis OR D. Chronic cavitary pulmonary disease AND 2. The requested agent is Sporanox (itraconazole) capsules OR D. BOTH of the following: <ol style="list-style-type: none"> 1. The patient has a diagnosis of oropharyngeal or esophageal candidiasis AND 2. The requested agent is Sporanox (itraconazole) oral solution OR E. The requested agent will be used for prophylaxis against invasive aspergillosis, AND the patient has/had ONE of the following: <ol style="list-style-type: none"> 1. A lung transplant OR

Module	Clinical Criteria for Approval				
	<p>2. A hematologic disorder with poorly functioning neutrophils (e.g., aplastic anemia, myelodysplastic syndrome [MDS]) OR</p> <p>3. Acute leukemia with repeat and/or prolonged neutropenia OR</p> <p>4. A history of invasive aspergillosis prior to transplantation OR</p> <p>F. The patient has another FDA labeled diagnosis for the requested agent and route of administration OR</p> <p>G. The patient has another indication that is supported in compendia for the requested agent and route of administration AND</p> <p>2. If the request is for one of the following brand agents with an available generic equivalent, then ONE of the following:</p> <table border="0" data-bbox="235 514 1112 577"> <thead> <tr> <th data-bbox="446 514 527 541">Brand</th> <th data-bbox="852 514 1112 541">Generic Equivalent</th> </tr> </thead> <tbody> <tr> <td data-bbox="235 552 462 577">Sporanox capsules</td> <td data-bbox="730 552 990 577">itraconazole capsules</td> </tr> </tbody> </table> <p>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>B. BOTH of the following:</p> <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 <p>C. The patient has tried and had an inadequate response to the generic equivalent [chart notes required] OR</p> <p>D. The generic equivalent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR</p> <p>E. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent [chart notes required] OR</p> <p>F. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent [chart notes 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 required] OR</p> <p>H. The generic equivalent is not in the best interest of the patient based on medical necessity [chart notes 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 required] OR</p> <p>J. There is support for the use of the requested brand agent over the generic equivalent AND</p> <p>3. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Compendia Allowed: AHFS or DrugDex 1, 2a, or 2b level of evidence</p> <p>Length of Approval</p> <p>BCBSOK: 36 months</p>	Brand	Generic Equivalent	Sporanox capsules	itraconazole capsules
Brand	Generic Equivalent				
Sporanox capsules	itraconazole capsules				

Module	Clinical Criteria for Approval
	<p>BCBSIL and BCBSMT: 12 months</p> <p>BCBSNM: 3 months</p> <p>ALL other plans:</p> <p>onychomycosis*: toenail infection - 3 months; fingernail infection - 5 weeks; oropharyngeal or esophageal candidiasis - 8 weeks; all other requests - 12 months</p> <p>*Target agents are limited to one approval within a 12-month period</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>The requested agent will also be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The request is for a BCBS NM Fully Insured or NM HIM member and ALL 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. The requested indication is a rare disease AND C. 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 2. ALL of the following: <ol style="list-style-type: none"> A. The member resides in Ohio AND B. The plan is Fully Insured or HIM Shop (SG) AND C. The patient does NOT have any FDA labeled contraindications to the requested agent AND D. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <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>

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:</p> <p>BCBSIL: 12 months</p> <p>Sporanox (itraconazole) solution for oropharyngeal or esophageal candidiasis - 8 weeks</p> <p>Sporanox (itraconazole) capsules for onychomycosis*: Toenail infection - 3 months; fingernail infection: - 5 weeks</p> <p>ALL other requests: 12 months</p> <p>*Target agents are limited to one approval within a 12 month period</p>