

Antifungals 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
Cresemba	isavuconazonium sulfate cap	186 MG ; 74.5 MG	M ; N ; O ; Y	N		
Tolsura	Itraconazole Cap 65 MG	65 MG	M ; N ; O ; Y	N		
Vivjoa	oteseconazole cap therapy pack	150 MG	M ; N ; O ; Y	N		
Noxafil	posaconazole for delayed release susp packet	300 MG	M ; N ; O ; Y	N		
Noxafil	posaconazole susp	40 MG/ML	M ; N ; O ; Y	O ; Y		
Noxafil	posaconazole tab delayed release	100 MG	M ; N ; O ; Y	O ; Y		
Vfend	voriconazole for susp	40 MG/ML	M ; N ; O ; Y	O ; Y		
Vfend	voriconazole tab	200 MG ; 50 MG	M ; N ; O ; Y	O ; Y		
Brexafemme	ibrexafungerp citrate tab	150 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
Brexafemme	Ibrexafungerp Citrate Tab	150 MG	4	Tablets	90	DAYS			
Vivjoa	Oteseconazole Cap Therapy Pack	150 MG	18	Capsules	180	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Brexafemme	ibrexafungerp citrate tab	150 MG	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Cresemba	isavuconazonium sulfate cap	186 MG ; 74.5 MG	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Noxafil	posaconazole for delayed release susp packet	300 MG	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Noxafil	posaconazole susp	40 MG/ML	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ;

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Noxafil	posaconazole tab delayed release	100 MG	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Tolsura	Itraconazole Cap 65 MG	65 MG	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Vfend	voriconazole for susp	40 MG/ML	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Vfend	voriconazole tab	200 MG ; 50 MG	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Vivjoa	oteseconazole cap therapy pack	150 MG	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Brexafemme	Ibexafungerp Citrate Tab	150 MG	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Vivjoa	Oteseconazole Cap Therapy Pack	150 MG	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Brexafemme	<p>Brexafemme (ibrexafungerp) will be approved when BOTH of the following are met</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. ALL 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. Vulvovaginal candidiasis (VVC) OR B. Reduction in the incidence of recurrent (experienced greater than or equal to 2 episodes of VVC within a 12 month period) vulvovaginal candidiasis (RVVC) AND 2. The patient is ONE of the following: <ol style="list-style-type: none"> A. An adult OR B. A post-menarchal pediatric patient AND 3. 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"> 1. Tried and had an inadequate response to fluconazole OR 2. An intolerance or hypersensitivity to fluconazole OR 3. An FDA labeled contraindication to fluconazole OR B. The patient has another FDA labeled indication for the requested agent and route of administration OR C. The patient has an indication that is supported in compendia for the requested agent and route of administration AND

Module	Clinical Criteria for Approval
	<p>2. 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>BCBSIL and BCBSMT: approve for 6 months</p> <p>ALL other plans: VVC - 3 months, RVVC - 6 months, all other indications - 6 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <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: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>
Cresemba	<p>Initial Evaluation</p> <p>Cresemba (isavuconazonium) 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 invasive aspergillosis OR B. The patient has a diagnosis of invasive mucormycosis OR C. The patient has another FDA labeled indication for the requested agent and route of administration OR D. The patient has an indication that is supported in compendia 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

Module	Clinical Criteria for Approval
	<p data-bbox="280 180 1357 268"> B. There is support for using the requested agent for the patient's age for the requested indication AND 3. The patient does NOT have any FDA labeled contraindications to the requested agent </p> <p data-bbox="232 306 1086 336">Compendia Allowed: AHFS or DrugDex 1, 2a, or 2b level of evidence</p> <p data-bbox="232 371 620 401">Length of Approval: 6 months</p> <p data-bbox="232 499 1190 529">The requested agent will also be approved when the following are met:</p> <ol data-bbox="280 567 1403 1029" 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 data-bbox="232 1066 1393 1125">Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p data-bbox="232 1163 1378 1247">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 1285 644 1314">Length of Approval: 12 months</p> <p data-bbox="232 1413 498 1442">Renewal Evaluation</p> <p data-bbox="232 1480 1266 1509">Cresemba (isavuconazonium) will be approved when ALL of the following are met:</p> <ol data-bbox="280 1547 1414 1946" style="list-style-type: none"> 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization review process (Note: patients not previously approved for the requested agent will require initial evaluation review) AND 2. ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. The patient has a diagnosis of invasive aspergillosis or invasive mucormycosis AND 2. The patient has continued indicators of active disease (e.g., biomarkers in serum assay, biopsy, microbiologic culture, radiographic evidence) OR B. BOTH of the following: <ol style="list-style-type: none"> 1. The patient has a diagnosis other than invasive aspergillosis or invasive mucormycosis AND 2. There is support for continued use of the requested agent for the requested indication AND

Module	Clinical Criteria for Approval
	<p>3. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Length of Approval: 6 months</p>
Noxafil	<p>Initial Evaluation</p> <p>Noxafil (posaconazole) 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 invasive aspergillosis AND ONE of the following: <ol style="list-style-type: none"> 1. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR 2. BOTH of the following: <ol style="list-style-type: none"> A. ONE of the following: <ol style="list-style-type: none"> 1. The patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer OR 2. 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 B. 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 3. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR 4. The patient has tried and had an inadequate response to voriconazole, amphotericin B, or isavuconazonium [chart notes required] OR 5. Voriconazole, amphotericin B, or isavuconazonium was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR 6. The patient has an intolerance or hypersensitivity to voriconazole, amphotericin B, or isavuconazonium [chart notes required] OR 7. The patient has an FDA labeled contraindication to voriconazole, amphotericin B, AND isavuconazonium [chart notes required] OR 8. Voriconazole, amphotericin B, or isavuconazonium is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient’s adherence of care; OR worsen a comorbid condition; OR decrease the patient’s ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR 9. Voriconazole, amphotericin B, or isavuconazonium is not in the best interest of the patient based on medical necessity [chart notes required] OR 10. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as voriconazole, amphotericin B, or isavuconazonium and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR B. The requested agent will be used for prophylaxis against invasive aspergillosis AND ONE of the following: <ol style="list-style-type: none"> 1. The patient is severely immunocompromised (e.g., hematopoietic stem cell transplant [HSCT] recipient with graft-versus-host disease [GVHD], hematologic malignancy with prolonged neutropenia from chemotherapy) OR 2. The patient is a lung transplant recipient OR

Module	Clinical Criteria for Approval
	<p>3. The patient has a history of invasive aspergillosis prior to transplantation OR</p> <p>C. The patient has a diagnosis of oropharyngeal candidiasis AND ONE of the following:</p> <ol style="list-style-type: none"> 1. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR 2. BOTH of the following: <ol style="list-style-type: none"> A. ONE of the following: <ol style="list-style-type: none"> 1. The patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer OR 2. 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 B. 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 3. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR 4. The patient has tried and had an inadequate response to itraconazole or fluconazole [chart notes required] OR 5. Itraconazole or fluconazole was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR 6. The patient has an intolerance or hypersensitivity to itraconazole or fluconazole [chart notes required] OR 7. The patient has an FDA labeled contraindication to BOTH fluconazole AND itraconazole [chart notes required] OR 8. Itraconazole or fluconazole is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR 9. Itraconazole or fluconazole is not in the best interest of the patient based on medical necessity [chart notes required] OR 10. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as itraconazole or fluconazole and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR <p>D. BOTH of the following:</p> <ol style="list-style-type: none"> 1. The requested agent will be used for prophylaxis against Candida infection AND 2. The patient is severely immunocompromised (e.g., hematopoietic stem cell transplant [HSCT] recipient with graft-versus-host disease [GVHD], hematologic malignancy with prolonged neutropenia from chemotherapy) OR <p>E. The patient has another FDA approved indication for the requested agent and route of administration OR</p> <p>F. The patient has another indication that is supported in compendia for the requested agent and route of administration AND</p> <p>2. If the patient has an FDA labeled indication, then ONE of the following:</p> <ol style="list-style-type: none"> A. The patient's age is within FDA labeling for the requested indication for the requested agent OR B. There is support for using the requested agent for the patient's age for the requested indication AND

Module	Clinical Criteria for Approval
	<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>BCBSIL and BCBSMT: approve for 6 months</p> <p>BCBSNM: approve for 3 months for oropharyngeal candidiasis and 6 months for all other indications.</p> <p>ALL other plans:</p> <p>1 months for oropharyngeal candidiasis</p> <p>6 months for all other indications</p> <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: 12 months</p> <p>Renewal Evaluation</p> <p>Noxafil (posaconazole) 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 review process (Note: patients not previously approved for the requested agent will require initial evaluation review). (A diagnosis of oropharyngeal candidiasis must go through initial criteria) AND 2. ONE of the following:

Module	Clinical Criteria for Approval
	<p>A. BOTH of the following:</p> <ol style="list-style-type: none"> 1. The patient has a diagnosis of invasive aspergillosis AND 2. The patient has continued indicators of active disease (e.g., biomarkers in serum assay, biopsy, microbiologic cultures, radiographic evidence) OR <p>B. BOTH of the following:</p> <ol style="list-style-type: none"> 1. The requested agent will be used for prophylaxis against Candida infection AND 2. The patient continues to be severely immunocompromised (e.g., HSCT recipient with GVHD, hematologic malignancy with prolonged neutropenia from chemotherapy) OR <p>C. BOTH of the following:</p> <ol style="list-style-type: none"> 1. The patient has a diagnosis other than invasive aspergillosis or prophylaxis against Candida infection AND 2. There is support for continued use of the requested agent for the requested indication AND <p>3. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Length of Approval: 6 months</p>
Tolsura (itraconazole)	<p>Initial Evaluation</p> <p>Tolsura (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. 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 ONE of the following: <ol style="list-style-type: none"> 1. Blastomycosis OR 2. Histoplasmosis OR 3. Disseminated, non-meningeal histoplasmosis OR 4. Chronic cavitary pulmonary disease OR B. The patient has a diagnosis of aspergillosis AND ONE of the following: <ol style="list-style-type: none"> 1. BOTH of the following: <ol style="list-style-type: none"> A. ONE of the following: <ol style="list-style-type: none"> 1. The patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer OR 2. 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 B. 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 2. The patient has tried and had an inadequate response to amphotericin B [chart notes required] OR 3. The patient has an intolerance or hypersensitivity to amphotericin B [chart notes required] OR 4. The patient has an FDA labeled contraindication to amphotericin B [chart notes required] OR C. The patient has another FDA labeled diagnosis 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

Module	Clinical Criteria for Approval				
	<p style="text-align: center;">B. There is support for using the requested agent for the patient's age for the requested indication OR</p> <p>B. The requested agent will be used for prophylaxis against invasive aspergillosis, AND the patient has/had ONE of the following:</p> <ol style="list-style-type: none"> 1. A lung transplant OR 2. A hematologic disorder with poorly functioning neutrophils (e.g., aplastic anemia, myelodysplastic syndrome [MDS]) OR 3. Acute leukemia with repeat and/or prolonged neutropenia OR 4. A history of invasive aspergillosis prior to transplantation OR <p>C. 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" style="width: 100%; margin: 10px 0;"> <thead> <tr> <th style="text-align: left; width: 20%;">Brand</th> <th style="text-align: left;">Generic Equivalent</th> </tr> </thead> <tbody> <tr> <td>Tolsura</td> <td>itraconazole capsule</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"> A. ONE of the following: <ol style="list-style-type: none"> 1. The patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer OR 2. 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 B. 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 is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR</p> <p>D. The patient has tried and had an inadequate response to the generic equivalent [chart notes required] OR</p> <p>E. The generic equivalent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR</p> <p>F. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the requested brand agent [chart notes required] OR</p> <p>G. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the requested brand agent [chart notes required] OR</p> <p>H. 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>I. The generic equivalent is not in the best interest of the patient based on medical necessity [chart notes required] OR</p> <p>J. 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>K. 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 contraindication(s) to the requested agent</p>	Brand	Generic Equivalent	Tolsura	itraconazole capsule
Brand	Generic Equivalent				
Tolsura	itraconazole capsule				

Module	Clinical Criteria for Approval
	<p>Compendia Allowed: AHFS or DrugDex 1, 2a, or 2b level of evidence</p> <p>Length of approval: BCBSIL and BCBSMT: 6 months ALL other plans: 3 months</p> <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: 12 months</p> <p>Renewal Evaluation</p> <p>Tolsura (itraconazole) 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 review process (Note: patients not previously approved for the requested agent will require initial evaluation review) AND 2. There is support for continued use of the requested agent for the requested indication AND 3. The patient does NOT have any FDA labeled contraindication(s) to the requested agent AND <p>Length of approval: 6 months</p>
Vfend	<p>Initial Evaluation</p> <p>Vfend (voriconazole) will be approved when BOTH of the following are met:</p> <ol style="list-style-type: none"> 1. 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 invasive aspergillosis OR

Module	Clinical Criteria for Approval
	<p>B. The patient has a diagnosis of esophageal candidiasis, candidemia, or other deep tissue Candida infection AND ONE of the following:</p> <ol style="list-style-type: none"> 1. BOTH of the following: <ol style="list-style-type: none"> A. ONE of the following: <ol style="list-style-type: none"> 1. The patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer OR 2. 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 B. 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 2. The patient has tried and had an inadequate response to fluconazole OR 3. The patient has an intolerance or hypersensitivity to fluconazole OR 4. The patient has an FDA labeled contraindication to fluconazole OR <p>C. The patient has a serious infection caused by <i>Scedosporium</i> or <i>Fusarium</i> species OR</p> <p>D. The patient has another FDA labeled indication for the requested agent and route of administration AND</p> <ol style="list-style-type: none"> 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 OR <p>B. The requested agent will be used for prophylaxis against invasive aspergillosis, AND the patient has ONE of the following:</p> <ol style="list-style-type: none"> 1. A lung transplant OR 2. A hematologic disorder with poorly functioning neutrophils (e.g., aplastic anemia, myelodysplastic syndrome [MDS]) OR 3. Acute leukemia with repeat and/or prolonged neutropenia OR 4. A history of invasive aspergillosis prior to transplantation OR 5. Hematopoietic stem cell transplant (HSCT) with graft-versus-host disease (GVHD) OR <p>C. The patient has another indication that is supported in compendia for the requested agent and route of administration AND</p> <ol style="list-style-type: none"> 2. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Compendia Allowed: AHFS, or DrugDex 1, 2a, or 2b level of evidence</p> <p>Length of Approval:</p> <p>BCBSIL and BCBSMT: approve for 6 months</p> <p>BCBSNM: esophageal candidiasis - 3 months, all other indications - 6 months</p> <p>ALL other plans: esophageal candidiasis - 1 month, all other indications - 6 months</p>

Module	Clinical Criteria for Approval
	<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: 12 months</p> <p>Renewal Evaluation</p> <p>Vfend (voriconazole) 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 review process (Note: patients not previously approved for the requested agent will require initial evaluation review) AND 2. ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. The patient has a diagnosis of invasive aspergillosis; serious infection caused by Scedosporium or Fusarium species; esophageal candidiasis, candidemia, or other deep tissue Candida infection AND 2. The patient has continued indicators of active disease (e.g., biomarkers in serum assay, biopsy, microbiologic cultures, radiographic evidence) OR B. BOTH of the following: <ol style="list-style-type: none"> 1. The patient has a diagnosis other than invasive aspergillosis; serious infection caused by Scedosporium or Fusarium species; esophageal candidiasis, candidemia, or other deep tissue Candida infection AND 2. There is support for continued use of the requested agent for the intended diagnosis AND 3. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Length of Approval:</p> <p>BCBSIL and BCBSMT: 6 months</p>

Module	Clinical Criteria for Approval
	<p>BCBSNM: esophageal candidiasis - 3 months, all other indications - 6 months</p> <p>ALL other plans: esophageal candidiasis - 1 month, all other indications - 6 months</p>
Vivjoa	<p>Vivjoa (oteseconazole) will be approved when BOTH 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 recurrent vulvovaginal candidiasis (RVVC) AND BOTH of the following: <ol style="list-style-type: none"> 1. The patient has experienced greater than or equal to 2 episodes of VVC within a 12 month period 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 will be using fluconazole in combination with the requested agent OR C. The patient has tried and had an inadequate response to fluconazole OR D. The patient has an intolerance or hypersensitivity to fluconazole OR E. The patient has an FDA labeled contraindication to fluconazole OR B. The patient has another FDA labeled indication for the requested agent and route of administration OR C. The patient has an indication that is supported in compendia for the requested agent and route of administration AND 2. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Compendia Allowed: AHFS or DrugDex 1, 2a, or 2b level of evidence</p> <p>Length of Approval: BCBSIL and BCBSMT: 6 months; all other plans: RVVC - 4 months, all other indications - 6 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <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

Module	Clinical Criteria for Approval
	<p>2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR</p> <p>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> <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: 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>ALL other plans:</p> <table border="1" data-bbox="235 1753 950 1984"> <tbody> <tr> <td data-bbox="235 1753 592 1822" rowspan="3">Brexafemme</td> <td data-bbox="592 1753 950 1822">3 months for treatment of vulvovaginal candidiasis</td> </tr> <tr> <td data-bbox="592 1822 950 1892">6 months for recurrent vulvovaginal candidiasis</td> </tr> <tr> <td data-bbox="592 1892 950 1961">6 months for all other indications</td> </tr> <tr> <td data-bbox="235 1961 592 1984">Vivjoa</td> <td data-bbox="592 1961 950 1984">4 months</td> </tr> </tbody> </table>	Brexafemme	3 months for treatment of vulvovaginal candidiasis	6 months for recurrent vulvovaginal candidiasis	6 months for all other indications	Vivjoa	4 months
Brexafemme	3 months for treatment of vulvovaginal candidiasis						
	6 months for recurrent vulvovaginal candidiasis						
	6 months for all other indications						
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