Oral Tetracycline Derivatives Prior Authorization Program Summary

This program applies to FlexRx Closed, FlexRx Open, GenRx Closed, GenRx Open, Health Insurance Marketplace and KeyRx formularies.

This is a FlexRx Standard and GenRx Standard program.

The BCBS MN Step Therapy Supplement also applies to this program for all Commercial/HIM lines of business.

POLICY REVIEW CYCLE

Effective Date	Date of Origin
07-01-2024	

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Acticlate® (doxycycline hyclate)* Tablet	Treatment of infections due to susceptible strains of microorganisms (refer to labeling for additional details) Adjunctive therapy for acute intestinal amebiasis adjunct to amebicides Prophylaxis of malaria due to Plasmodium falciparum in short-term travelers (less than 4 months) to areas with chloroquine and/or pyrimethamine-sulfadoxine resistant strains Adjunctive therapy for severe acne	*generic available	24
Doryx® MPC (doxycycline hyclate delayed-release) Tablet	Treatment of infections due to susceptible strains of microorganisms (refer to labeling for additional details) Adjunctive therapy for acute intestinal amebiasis adjunct to amebicides Prophylaxis of malaria due to Plasmodium falciparum in short-term travelers (less than 4 months) to areas with chloroquine and/or pyrimethamine-sulfadoxine resistant strains Adjunctive therapy for severe acne		1
Doryx® (doxycycline hyclate delayed-release)* Tablet	Treatment of infections due to susceptible strains of microorganisms (refer to labeling for additional details) Adjunctive therapy for acute intestinal amebiasis adjunct to amebicides Prophylaxis of malaria due to Plasmodium falciparum in short-term travelers (less than 4 months) to areas with chloroquine and/or pyrimethamine-sulfadoxine resistant strains Adjunctive therapy for severe acne	*generic available	3
doxycycline hyclate	For the treatment of infections due to susceptible strains of microorganisms (refer to labeling for additional details) In acute intestinal amebiasis, doxycycline may be a useful adjunct to amebicides	*generic available	4; 7; 29

Agent(s)	FDA Indication(s)	Notes	Ref#
Delayed-release capsule* Delayed-release tablet* Tablet*	For the prophylaxis of malaria due to Plasmodium falciparum in short-term travelers (less than 4 months) to areas with chloroquine and/or pyrimethamine-sulfadoxine resistant strains In severe acne, doxycycline may be useful adjunctive therapy		
doxycycline monohydrate Capsule	Treatment of infections due to susceptible strains of microorganisms (refer to labeling for additional details) Adjunctive therapy for acute intestinal amebiasis adjunct to amebicides Adjunctive therapy for severe acne		5
Doxycycline (doxycycline monohydrate) * Tablet	Treatment of infections due to susceptible strains of microorganisms (refer to labeling for additional details) Adjunctive therapy for acute intestinal amebiasis adjunct to amebicides Adjunctive therapy for severe acne	*generic available	2
Minocin® (minocycline hydrochloride) * Capsule	Treatment of infections due to susceptible strains of microorganisms (refer to labeling for additional details) Adjunctive therapy for acute intestinal amebiasis adjunct to amebicides Adjunctive therapy for severe acne	*generic available	10
Minocycline extended-release Capsule	To treat only inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older		27
minocycline Tablet*	For the treatment of infections due to susceptible strains of microorganisms (see labeling for details) In acute intestinal amebiasis, minocycline may be a useful adjunct to amebicides For the treatment of asymptomatic carriers of Neisseria meningitidis to eliminate meningococci from the nasopharynx In severe acne, minocycline may be useful adjunctive therapy	*generic available	11
Minocycline Extended-Release Tablet*	To treat only inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older	*generic available	30

Agent(s)	FDA Indication(s)	Notes	Ref#
Minolira™ (minocycline hydrochloride extended-release) Tablet	To treat only inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older Limitations of Use: Minolira has not been evaluated in the treatment of infections.		26
Oracea® (doxycycline delayed-release) Capsule*	For the treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients. No meaningful effect was demonstrated for generalized erythema (redness) of rosacea. Limitations of use: • This formulation of doxycycline has not been evaluated in the treatment or prevention of infections. • Oracea has not been evaluated for the treatment of erythematous, telangiectatic, or ocular components of rosacea.	*generic available	6
Seysara® (sarecycline hydrochloride) Tablet	To treat inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age or older Limitations of Use: • Efficacy of Seysara beyond 12 weeks and safety beyond 12 months have not been established. • Seysara has not been evaluated in the treatment of infections.		28
Solodyn® (minocycline hydrochloride film coated extended-release)* Tablet	To treat only inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older Limitations of use: • Solodyn did not demonstrate any effect on non-inflammatory lesions. • Safety of Solodyn has not been established beyond 12 weeks of use. • This formulation of minocycline has not been evaluated in the treatment of infections.	*generic available	12
Targadox® (doxycycline hyclate)* Tablet	Treatment of infections due to susceptible strains of microorganisms (refer to labeling for additional details) Adjunctive therapy for acute intestinal amebiasis adjunct to amebicides Prophylaxis of malaria due to Plasmodium falciparum in short-term travelers (less than 4 months) to areas with chloroquine and/or pyrimethamine-sulfadoxine resistant strains Adjunctive therapy for severe acne	*generic available	25
Tetracycline Tablets	Treatment of infections due to susceptible strains of microorganisms (refer to labeling for additional details)		32

Agent(s)	FDA Indication(s)	Notes	Ref#
	Adjunctive therapy for acute intestinal amebiasis adjunct to amebicides Adjunctive therapy for severe acne		
Vibramycin® Capsule (doxycycline hyclate)* Suspension (doxycycline monohydrate) *	Treatment of infections due to susceptible strains of microorganisms (refer to labeling for additional details) Adjunctive therapy for acute intestinal amebiasis adjunct to amebicides Prophylaxis of malaria due to Plasmodium falciparum in short-term travelers (less than 4 months) to areas with chloroquine and/or pyrimethamine-sulfadoxine resistant strains Adjunctive therapy for severe acne	*generic available	8
Ximino® (minocycline hydrochloride extended-release) Capsule	To treat only inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older Limitations of Use: Ximino did not demonstrate any effect on non-inflammatory acne lesions. Safety of Ximino has not been established beyond 12 weeks of use. This formulation of minocycline has not been evaluated in the treatment of infections.		27

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Acne Vulgaris	The American Academy of Dermatology suggests several options for treatment of acne vulgaris in adolescents and young adults. Recommendations for topical acne therapies include benzoyl peroxide or combination with topical antibiotics (e.g., erythromycin or clindamycin) as monotherapy for mild acne, or in conjunction with topical retinoid, or systemic antibiotic therapy for moderate to severe acne. Clindamycin 1% solution or gel is currently the preferred topical antibiotic for acne therapy. Erythromycin 2% is available in multiple formulations but has reduced efficacy compared to clindamycin due to resistance of cutaneous Staphylococci and P acnes.(14) Topical adapalene, tretinoin, and benzoyl peroxide can be safely used in the management of preadolescent acne in children. Azelaic acid is useful as an adjunctive acne treatment and is recommended in the treatment of post-inflammatory dyspigmentation. Topical dapsone 5% gel is recommended for inflammatory acne, particularly in adult females with acne. There is limited data to support sulfur, nicotinamide, resorcinol, sodium sulfacetamide, aluminum chloride, and zinc in the treatment of acne.(14) If topical antibiotic treatment is to be prolonged for more than a few weeks, topical benzoyl peroxide should be added, or used in combination products.(31) Systemic antibiotics have been a mainstay for acne treatment for years.(14) They are indicated for use in moderate to severe inflammatory acne and should be used in combination with a topical retinoid and benzoyl peroxide. Tetracyclines are considered first-line therapy in moderate to severe acne, except when contraindicated. Doxycycline and minocycline are more effective than tetracycline, but neither is superior to each other. Oral erythromycin and azithromycin should be reserved for those who cannot use tetracyclines. The use of other systemic antibiotics is discouraged due to limited data for use in acne. Trimethoprim-sulfamethoxazole and trimethoprim use should be restricted to patients who are unable to tolerate tetracycline or in treatment-resistant patients.(14) Concomitant topical therapy with

	benzoyl peroxide or a retinoid should be used with systemic antibiotics and for maintenance after completion of systemic antibiotic therapy.(14) Reviews of tetracycline agents used in the treatment of acne(15,16) have found tetracycline, minocycline, and doxycycline all to be effective in the treatment of acne, particularly during the inflammatory stage. One review of seven randomized trials which were set up to compare the efficacy of tetracyclines found no evidence of superiority of one tetracycline over another in reducing acne lesion counts.(15) Evidence-based recommendations for treatment of pediatric acne from the American Academy of Pediatrics consider oral antibiotics appropriate for moderate to severe inflammatory acne. Tetracycline derivatives, including tetracycline, doxycycline and minocycline are not to be used in children younger than 8 years of age.(23) There are several other treatment options for acne. Hormonal therapy or oral contraceptives and isotretinoin are suggested; however, caution is needed for both therapies for adverse events and monitoring. There is limited evidence for the use and benefit of physical modalities for the routine treatment of acne, including pulsed dye laser, glycolic acid peels, and salicylic acid peels. Intralesional corticosteroid injections are effective in the treatment of individual acne nodules. Furthermore, no current data supports any specific dietary changes to manage acne. However, data suggests that high glycemic index diets maybe associated with acne and limited evidence suggests that some dairy products, particularly skim milk, may influence acne.(14)
Rosacea	Although there is no cure for rosacea, its features may be reduced or controlled with a range of topical and oral therapies as well as appropriate skin care and lifestyle management. Combination therapy to target the specific features of each patient with rosacea is often necessary for effective treatment. Patients and features of the disease may respond well or less well to various agents, and when treatments are effective, the mechanism(s) of action may be unclear. First-line therapies include topical agents, such as azelaic acid and metronidazole. When first-line treatments for inflammation are inadequate or when rosacea is more severe, oral antibiotics or retinoids are sometimes used, although data is sparse. Oral antibiotics often used include tetracycline, doxycycline, and minocycline.(9)
Minocycline	The safety and efficacy of Solodyn in the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris was assessed in two 12-week, multi-center, randomized, double-blind, placebo-controlled, studies in subjects greater than 12 years. The mean age of subjects was 20 years and subjects were from the following racial groups: white (73%), Hispanic (13%), black (11%), Asian/Pacific islander (2%), and other (2%). In the two efficacy and safety trials, a total of 924 subjects with non-nodular moderate to severe acne vulgaris received 1 mg/kg of Solodyn or placebo for a total of 12 weeks. The two primary efficacy endpoints were: 1. Mean percent change in inflammatory lesion counts from baseline to 12 weeks. Percentage of subjects with an Evaluator's Global Severity Assessment (EGSA) of clear or almost clear at 12 weeks. 2. Patients on Solodyn had a greater mean percent improvement in inflammatory lesions (43.1% and 45.8% in studies one and two respectively) compared to placebo (31.7% and 30.8%) ($p<0.05$). Solodyn did not demonstrate any effect on non-inflammatory lesions.(13) There are no clinical studies comparing extended-release minocycline with older immediate-release formulations. A Medical Letter review of Solodyn concluded "Solodyn is an expensive new formulation of minocycline labeled for once-daily use. Whether Solodyn is as effective as immediate-release minocycline and less likely to cause vertigo remains to be established.(17)
Doxycycline	Oracea, indicated for the treatment of inflammatory lesions (papules and pustules) of rosacea in adult patients, is comprised of 30 mg immediate release and 10 mg delayed release doxycycline. While the mechanism of action is not fully understood, it is thought to be due to an anti-inflammatory effect.(6)

	The safety and efficacy of Oracea was evaluated in two double-blind, randomized, placebo controlled trials involving 537 patients for the treatment of rosacea. Both phase III trials were 16 weeks in duration. Oracea therapy resulted in a mean decrease in lesion count from baseline of 11.8 and 9.5 in study one and two respectively compared to 5.9 and 4.3 for placebo respectively ($p<0.05$). Patients on Oracea did not demonstrate improvement in erythema compared to placebo.(6) The FDA noted that the magnitude of efficacy shown is clinically somewhat limited and modest for an oral medication. The manufacturer has stated that at the systemic concentration provided by Oracea, doxycycline is not effective as an antimicrobial agent and appears to exert its action independent of antibacterial activity. The sponsor has not submitted data supporting this mechanism of action. Furthermore, there are some possible indicators of antibacterial action in the form of an increase in diarrhea in the active treatment arms of the pivotal trials.(18) A double-blind randomized trial compared Oracea 40 mg once daily to doxycycline 100 mg once daily in the treatment of moderate to severe rosacea for 16 weeks. There was no statistically significant difference in the primary efficacy endpoint of the change in total lesion count. There was a higher incidence of GI adverse events related to doxycycline 100 mg versus Oracea (26% vs 5%); however, the discontinuation rate was 50% higher with Oracea versus doxycycline 100 mg.(19)
Safety	Doxycycline and minocycline are contraindicated in persons who have shown hypersensitivity to any of the tetracyclines.(1-4,6-8,11-12,24-30) Minocin is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines or to any of the components of the product formulation.(10) Doxycycline capsules are contraindicated in persons who have shown hypersensitivity to any of the tetracyclines or to any of the components of the product formulation.(5) Tetracycline tablets are contraindicated in persons who have shown hypersensitivity to any of the tetracyclines.(32)

REFERENCES

Number	Reference
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2	Doxycycline monohydrate tablet prescribing information. Zydus Pharmaceuticals USA Inc. September 2022.
3	Doryx prescribing information. Mayne Pharma. July 2022.
4	Doxycycline hyclate prescribing information. Mayne Pharma, Inc. October 2022.
5	Doxycycline capsules prescribing information. Chartwell RX, LLC. February 2023.
6	Oracea prescribing information. Galderma Laboratories, L.P. January 2023.
7	Doxycycline hyclate prescribing information (20 mg). Lannett Company, Inc. July 2020.
8	Vibramycin prescribing information. Pfizer Inc. December 2022.
9	Thiboutot D, Anderson R, Cook-Bolden F, et. al. Standard management options for rosacea: The 2019 update by the National Rosacea Society Expert Committee. *J Am Acad Dermatol.* 2020;82:1501-10.
10	Minocin prescribing information. Melinta Therapeutics, LLC. February 2021.
11	Minocycline tablet prescribing information. Sun Pharmaceutical Industries, Inc. June 2018.
12	Solodyn prescribing information. Bausch Health US LLC. September 2017.
13	Clinical Pharmacology. Monographs: Minocycline.
14	Zaenglein, Andrew L, MD, et al. American Academy of Dermatology. Guidelines of care for the management of acne vulgaris. *J Am Acad Dermatol*. 2016;74:945-73.

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15	Simonart T, Dramaix M, De Maertelaer V. Efficacy of tetracyclines in the treatment of acne vulgaris: a review. *Br J Dermatol.* 2007;158:208-16.
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18	Center for Drug Evaluation and Research. FDA Medical Review: Oracea. Application Number 50-805. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/050805s000_MedR.pdf.
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22	Treatment guidelines from the Medical Letter: Drugs for acne, rosacea, and psoriasis. *Medical Letter.* 2013;11(125):1-8.
23	Eichenfield L, Krakowski A, Piggott C, et al. Evidence-based recommendations for the diagnosis and treatment of pediatric acne. *Pediatrics.* 2013;131;S163-S186.
24	Acticlate prescribing information. Almirall, LLC. March 2020.
25	Targadox prescribing information. Journey Medical Corporation. March 2020.
26	Minolira prescribing information. EPI Health, Inc. June 2018.
27	Ximino prescribing information. Journey Medical Corporation. January 2021.
28	Seysara prescribing information. Almirall, LLC. March 2023.
29	Doxycycline hyclate delayed release tablet prescribing information. Basiem, LLC. April 2019.
30	Minocycline ER prescribing information. Arminda Pharmaceuticals. December 2022
31	Kaiane A, Habeshian, Bernard A. Cohen; Current Issues in the Treatment of Acne Vulgaris. *Pediatrics.* 2020; 145(2);S225-S230.
32	Tetracycline prescribing information. Pharmaka Generics Inc. January 2024.

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Oracea	doxycycline (rosacea) cap delayed release	40 MG	M ; N ; O	O ; Y		
Vibramycin	doxycycline hyclate cap	100 MG ; 50 MG	M ; N ; O	O ; Y		
Acticlate ; Lymepak ; Targadox	doxycycline hyclate tab	100 MG ; 150 MG ; 20 MG ; 50 MG ; 75 MG	M ; N ; O	O ; Y		
Doryx ; Doryx mpc	doxycycline hyclate tab delayed release	100 MG ; 120 MG ; 150 MG ; 200 MG ; 50 MG ; 60 MG ; 75 MG ; 80 MG	M ; N ; O ; Y	N ; O ; Y		
Mondoxyne nl	doxycycline monohydrate cap	100 MG ; 150 MG ; 50 MG ; 75 MG	M ; N ; O	Y		
Vibramycin	doxycycline monohydrate for susp	25 MG/5ML	M ; N ; O	O ; Y		

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Avidoxy	doxycycline monohydrate tab	100 MG ; 150 MG ; 50 MG ; 75 MG	M ; N ; O	Y		
Minocin	minocycline hcl cap	100 MG ; 50 MG ; 75 MG	M ; N ; O	O ; Y		
Ximino	minocycline hcl cap er	135 MG ; 45 MG ; 90 MG	M ; N ; O	M		
	minocycline hcl tab	100 MG ; 50 MG ; 75 MG	M ; N ; O	Y		
Coremino ; Minolira ; Solodyn	minocycline hcl tab er	105 MG ; 115 MG ; 135 MG ; 45 MG ; 55 MG ; 65 MG ; 80 MG ; 90 MG	M ; N ; O ; Y	N ; O ; Y		
Seysara	sarecycline hcl tab	100 MG ; 150 MG ; 60 MG	M ; N ; O ; Y	N		
	tetracycline hcl tab	250 MG ; 500 MG	M ; N ; O ; Y	N		

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
	minocycline hcl tab	100 MG ; 50 MG ; 75 MG	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
	tetracycline hcl tab	250 MG ; 500 MG	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Acticlate ; Lymepak ; Targadox	doxycycline hyclate tab	100 MG ; 150 MG ; 20 MG ; 50 MG ; 75 MG	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Avidoxy	doxycycline monohydrate tab	100 MG ; 150 MG ; 50 MG ; 75 MG	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Coremino ; Minolira ; Solodyn	minocycline hcl tab er	105 MG ; 115 MG ; 135 MG ; 45 MG ; 55 MG ; 65 MG ; 80 MG ; 90 MG	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Doryx ; Doryx mpc	doxycycline hyclate tab delayed release	100 MG ; 120 MG ; 150 MG ; 200 MG ; 50 MG ; 60 MG ; 75 MG ; 80 MG	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Minocin	minocycline hcl cap	100 MG ; 50 MG ; 75 MG	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Marketplace/BasicRx ; KeyRx
Mondoxyne nl	doxycycline monohydrate cap	100 MG ; 150 MG ; 50 MG ; 75 MG	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Oracea	doxycycline (rosacea) cap delayed release	40 MG	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Seysara	sarecycline hcl tab	100 MG ; 150 MG ; 60 MG	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Vibramycin	doxycycline hyclate cap	100 MG ; 50 MG	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Vibramycin	doxycycline monohydrate for susp	25 MG/5ML	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Ximino	minocycline hcl cap er	135 MG ; 45 MG ; 90 MG	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Target Agent(s) will be approved when ALL of the following are met: 1. The patient has an FDA approved indication for the requested agent **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. If the patient's diagnosis is acne, ONE of the following: A. The patient will be using a benzoyl peroxide agent OR a retinoid agent in combination with the requested agent **OR** B. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to a benzoyl peroxide agent OR a retinoid agent **OR** C. The patient's medication history includes use of a benzoyl peroxide agent OR a retinoid agent in the past 999 days **OR** D. BOTH of the following: 1. The prescriber has stated that the patient has tried a benzoyl peroxide agent OR a retinoid agent **AND** 2. The benzoyl peroxide agent or retinoid agent was discontinued due to lack of effectiveness or an adverse event **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following:

Module	Clinical Criteria for Approval
	1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that ALL benzoyl peroxide agents AND ALL retinoid agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. If the patient's diagnosis is acne or rosacea, the patient will NOT be using the requested agent in combination with another tetracycline derivative for the treatment of acne or rosacea **AND** 5. ONE of the following: A. The requested agent is a preferred oral generic doxycycline agent **OR** B. The requested agent is a preferred oral generic minocycline agent **OR** C. BOTH of the following: 1. ONE of the following: A. The patient has tried and had an inadequate response to a preferred oral generic doxycyline agent **OR** B. The patient has an intolerance or hypersensitivity to a preferred oral generic doxycycline agent **OR** C. The patient has an FDA labeled contraindication to ALL preferred oral generic doxycycline agents **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL preferred oral generic doxycycline agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to a preferred oral generic minocycline agent **OR** B. The patient has an intolerance or hypersensitivity to a preferred oral generic minocycline agent **OR** C. The patient has an FDA labeled contraindication to ALL preferred oral generic minocycline agents **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL preferred oral generic minocycline agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to

Module	Clinical Criteria for Approval
	achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Length of Approval:** 12 months

