Dry Eye Disease Prior Authorization with Quantity Limit Program Summary

This program applies to FlexRx Closed, FlexRx Open, FocusRx, 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
10-01-2024	04-01-2016

FDA LABELED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Cequa® (cyclosporine) Ophthalmic solution	Increase tear production in patients with keratoconjunctivitis sicca (dry eye)		1
Eysuvis® (loteprednol etabonate) Ophthalmic suspension	Short-term (up to two weeks) treatment for the signs and symptoms of dry eye disease		11
Miebo® (perfluorohexyloctane) Ophthalmic solution	Treatment of the signs and symptoms of dry eye disease		10
Restasis® (cyclosporine) * Ophthalmic emulsion	Indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.	*generic available	2
Tyrvaya® (varenicline) Nasal spray	Treatment of the signs and symptoms of dry eye disease		12
Vevye® (cyclosporine)	Treatment of the signs and symptoms of dry eye disease		13

Agent(s)	FDA Indication(s)	Notes	Ref#
Ophthalmic solution			
Xiidra® (lifitegrast) Ophthalmic solution	Treatment of the signs and symptoms of dry eye disease		3

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

CLINICAL RATIONALE

Dry Eye Disease	Dry eye disease (also known as dry eye syndrome) is a multifactorial disease of the ocular surface with loss of homeostasis of the tear film. It is accompanied by ocular symptoms where tear film instability and hyperosmolarity, ocular surface inflammation and damage, and neurosensory abnormalities play etiological roles.(6) The tear film secreting glands and ocular surface function as an integrated system. Disease or dysfunction of this system results in unstable and poorly maintained tear film that causes symptoms of ocular irritation and possible damage to the ocular surface. Dry eye disease may be exacerbated by systemic medications (e.g., diuretics, antihistamines, anticholinergics, systemic retinoids, antidepressants) and rosacea.(4) Dry eye disease is often associated with Sjogren syndrome, an autoimmune multisystem disorder that most often affects the tear and salivary glands. Tear deficiency may occur in other systemic diseases, such as lymphoma, sarcoidosis, hemochromatosis, and amyloidosis. Dry eye disease may also develop due to systemic viral infections, such as retroviruses, Epstein-Barr virus, and HIV.(4) The American Academy of Ophthalmology and the Tear Film and Ocular Surface Society (TFOS) categorized dry eye into three severity levels based on both symptoms and signs. Due to the nature of the disease, this classification is imprecise because the characteristics overlap at each level of severity.(4,6,7) • Mild dry eye: symptoms of irritation, itching, soreness, ocular discomfort, burning or intermittent blurred vision • Moderate dry eye: increased discomfort and frequency of symptoms, and negative effect on visual function may become more consistent • Severe dry eye: increasing frequency of visual symptoms that may become constant as well as potentially disabling The American Academy of Ophthalmology recommend treating mild dry eye with the following:(4,8) • Education and environmental modifications • Elimination of offending topical or systemic medications • Aqueous enhancement using artificial tear substitutes, gels, or ointment • Eyelid therapy (warm compresses and eyelid scrubs) • Treatment of contributing ocular factors such as blepharitis or meibomianitis • Correction of eyelid abnormality For treatment of moderate dry eye, the following are recommended in addition to mild dry eye treatment options:(4,8)

	• Topical anti-inflammatory agents (topical cyclosporine and corticosteroids), systemic omega 3 fatty acids supplements • Punctal plugs • Spectacle side shields and moisture chambers For treatment of severe dry eye, the following are recommended in addition to mild and moderate dry eye treatment options:(4,8) • Systemic cholinergic agonists • Mucolytic agents • Autologous serum tears • Therapeutic contact lenses • Surgical punctal occlusion • Tarsorrhaphy Because of the inconsistent correlation between reported symptoms and clinical signs as well as the relatively poor specificity and/or sensitivity of clinical tests, patients with suggestive symptoms without signs should be placed on trial treatments with artificial tears when other potential causes of ocular irritation have been eliminated. As the severity of the dry eyes increases, aqueous enhancement of the eye using topical agents is appropriate. Emulsions, gels, and ointments can be used. The use of artificial tears may be increased, but the practicality of frequent tear instillation depends on the lifestyle or manual dexterity of the patient. Non-preserved tear substitutes are generally preferable; however, tears with preservatives may be sufficient for patients with mild dry eye and an otherwise healthy ocular surface. When tear substitutes are used frequently and chronically (e.g., more than 4 times a day), non-preserved tears are generally recommended. It is imperative to treat any causative factors that are amenable to treatment.(4) Anti-inflammatory therapies may be considered in addition to aqueous enhancement therapies. However, since dry eye symptoms tend to wax and wane over long periods of time, the lack of long-term data on the effectiveness of cyclosporine and the costs of longer-term (e.g., annual, lifetime) treatment should be weighed.(4) Pre-treatment with topical ophthalmic corticosteroids either before or during initiation with a non-glucocorticoid anti-inflammatory agent may provide more rapid improvement in symptoms of dry eye disease and decrease the incidence of severe stinging associated with a topical immunomodulator agent compared to a topical immunomodulator alone.(8) The AAO also notes that topical corticosteroid use for dry eye disease is controversial, but use for induction therapy prior to initiating non-glucocorticoid anti-inflammatory agents as maintenance. Once the patient is in a successful maintenance phase, steroids are used for acute flare-ups triggered by travel, allergies, respiratory infections, or exposures to environmental irritants with maintenance therapy.(9) The Sjogren's Syndrome Foundation's Clinical Practice Guidelines on Ocular Management in Sjögren's Patients states the following.(5) • Management depends upon the nature of the dry and the severity of symptoms. • In early disease, tear replacement with topically applied artificial tear or lubricant solutions may be sufficient, but progressive or more severe inflammation of the lacrimal gland and ocular surface occur both as an inciting event in many cases and as a secondary effect as the dry eye disease worsens, called keratoconjunctivitis sicca (KCS), requires the use of dietary supplements (omega 3 essential fatty acids), anti-inflammatory measures (e.g., topical corticosteroids or cyclosporine), or oral secretagogues.

	• Plugging of the lacrimal puncta can be done once the inflammatory component of dry eye is controlled. Control of lid margin (meibomian gland) disease may require topical antibiotic or systemic doxycycline therapy. The most severe cases of dry eye, particularly those unresponsive to more standard therapy, may require use of topical autologous serum or partial closure of the interpalpebral fissure to reduce surface exposure. Scleral contact lenses may be needed to control severe ocular surface damage.
Drops per bottle	Miebo manufacturer notes a smaller than average drop size of 11 uL compared to other aqueous formulations containing water estimated to be approximately 30-50 uL/drop.(14)
Safety	Cequa (cyclosporine), Miebo (perfluorohexyloctane), Tyrvaya (varenicline), and Vevye (cyclosporine) have no FDA labeled contraindications for use.(1,10,12,13) Eysuvis (loteprednol etabonate) is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal disease of ocular structures.(11) Restasis (cyclosporine) is contraindicated in patients with hypersensitivity to any of the ingredients in the formulation.(2) Xiidra (lifitegrast) is contraindicated in patients with known hypersensitivity to lifitegrast or to any of the other ingredients in the formulation.(3)

REFERENCES

Number	Reference
1	Cequa prescribing information. Sun Pharma Global. December 2022.
2	Restasis prescribing information. Allergan, Inc. July 2017.
3	Xiidra prescribing information. Shire US, Inc. June 2020.
4	Akpek EK, Amescua G, Farid M, et al. Dry Eye Syndrome Preferred Practice Pattern®. *Ophthalmology*. 2019;126(1):P286-P334. doi:10.1016/j.ophtha.2018.10.023
5	Foulks GN, Forstot SL, Donshik PC, et al. *The Sjögren's Foundation Clinical Practice Guidelines for Ocular Management in Sjögren's*.; 2015. https://sjogrens.org/sites/default/files/inline-files/SF_CPG-Ocular_2022_0.pdf
6	Craig JP, Nichols KK, Akpek EK, et al. TFOS DEWS II Definition and Classification Report. *The Ocular Surface*. 2017;15(3):276-283. doi:10.1016/j.jtos.2017.05.008
7	Wolffsohn JS, Arita R, Chalmers RL, et al. TFOS DEWS II Diagnostic Methodology report. *The Ocular Surface*. 2017;15(3):539-574. doi:10.1016/j.jtos.2017.05.001
8	Jones L, Downie LE, Korb DR, et al. TFOS DEWS II Management and Therapy Report. *The Ocular Surface*. 2017;15(3):575-628. doi:10.1016/j.jtos.2017.05.006
9	Savvy steroid use. American Academy of Ophthalmology. Published May 5, 2016. https://www.aao.org/eyenet/article/savvy-steroid-use
10	Miebo prescribing information. Bausch & Lomb Inc. January 2024.
11	Eysuvis prescribing information. Alcon Laboratories, Inc. November 2023.
12	Tyrvaya prescribing information. Oyster Point Pharma, Inc. February 2024.
13	Vevye prescribing information. Novaliq GmbH. May 2023.
14	The MIEBO experience MIEBO™ (perfluorohexyloctane ophthalmic solution) | Official HCP Site. https://www.miebo-ecp.com/the-miebo-experience/

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Restasis ; Restasis multidose	Cyclosporine (Ophth) Emulsion 0.05%	0.05 %	M ; N ; O ; Y	O ; Y		
Cequa ; Vevye	cyclosporine (ophth) soln	0.09 % ; 0.1 %	M ; N ; O ; Y	N		
Xiidra	lifitegrast ophth soln	5 %	M ; N ; O ; Y	N		
Eysuvis	Loteprednol Etabonate Ophth Susp	0.25 %	M ; N ; O ; Y	N		
Miebo	perfluorohexyloctane ophth soln	1.338 GM/ML	M ; N ; O ; Y	N		
Tyrvaya	varenicline tartrate nasal soln	0.03 MG/ACT	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
Cequa	Cyclosporine (Ophth) Soln 0.09% (PF)	0.09 %	60	Vials	30	DAYS			
Eysuvis	Loteprednol Etabonate Ophth Susp	0.25 %	2	Bottles	90	DAYS			
Miebo	perfluorohexyloctane ophth soln	1.338 GM/ML	1	Bottle	30	DAYS			
Restasis	cyclosporine (ophth) emulsion	0.05 %	60	Vials	30	DAYS			00023916330 ; 00023916360 ; 00378876058 ; 00378876091 ; 10702080803 ; 10702080806;50090124200 ; 50090447600;60505620201 ; 60505620202 ; 68180021430 ; 68180021460 ; 73043000501 ; 73043000502
Restasis multidose	cyclosporine (ophth) emulsion	0.05 %	1	Bottle	30	DAYS			00023530105;
Tyrvaya	Varenicline Tartrate Nasal Soln	0.03 MG/ACT	2	Bottles	30	DAYS			
Vevye	cyclosporine (ophth) soln	0.1 %	1	Bottle	30	DAYS			
Xiidra	Lifitegrast Ophth Soln 5%	5 %	60	Vials	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Cequa ; Vevye	cyclosporine (ophth) soln	0.09 % ; 0.1 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Eysuvis	Loteprednol Etabonate Ophth Susp	0.25 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Miebo	perfluorohexyloctane ophth soln	1.338 GM/ML	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Restasis ; Restasis multidose	Cyclosporine (Ophth) Emulsion 0.05%	0.05 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Tyrvaya	varenicline tartrate nasal soln	0.03 MG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Xiidra	lifitegrast ophth soln	5 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Cequa	Cyclosporine (Ophth) Soln 0.09% (PF)	0.09 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Eysuvis	Loteprednol Etabonate Ophth Susp	0.25 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Miebo	perfluorohexyloctane ophth soln	1.338 GM/ML	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Restasis	cyclosporine (ophth) emulsion	0.05 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Restasis multidose	cyclosporine (ophth) emulsion	0.05 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Marketplace/BasicRx ; KeyRx
Tyrvaya	Varenicline Tartrate Nasal Soln	0.03 MG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Vevye	cyclosporine (ophth) soln	0.1 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Xiidra	Lifitegrast Ophth Soln 5%	5 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Initial Evaluation** **Cequa (cyclosporine), Miebo (perfluorohexyloctane), Tyrvaya (varenicline), Vevye (cyclosporine), and Xiidra (lifitegrast)** will be approved when ALL of the following are met: 1. ONE of the following: A. BOTH of the following: 1. The patient has a diagnosis of dry eye disease (i.e., dry eye syndrome, keratoconjunctivitis sicca [e.g., Sjögren's Syndrome]) **AND** 2. ONE of the following: A. The patient has previously tried or is currently using aqueous enhancements (e.g., artificial tears, gels, ointments [target agents not included]) **OR** B. The patient has an intolerance or hypersensitivity to aqueous enhancements (e.g., artificial tears, gels, ointments [target agents not included]) **OR** C. The patient has an FDA labeled contraindication to ALL aqueous enhancements **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 the 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 aqueous enhancements 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 **OR** B. The patient has another FDA labeled indication for the requested agent **OR** C. The patient has an indication that is supported in compendia for the requested agent and route of administration **AND** 2. The patient will NOT be using the requested agent in combination with Verkazia (cyclosporine) or another target agent in this program (e.g., Cequa, Eysuvis, Miebo, Restasis, Tyrvaya, Vevye, Xiidra) **AND**

Module	Clinical Criteria for Approval
	3. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS or DrugDex 1 or 2a level of evidence **Length of Approval:** Miebo (perfluorohexyloctane) and Tyrvaya (varenicline) - 2 months; Cequa (cyclosporine), Vevye (cyclosporine), Xiidra (lifitegrast) - 3 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Initial Evaluation** **Eysuvis (loteprednol etabonate)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of dry eye disease (i.e., dry eye syndrome, keratoconjunctivitis sicca [e.g., Sjögren's Syndrome]) AND ONE of the following: 1. The patient has NOT been previously treated with the requested agent AND ONE of the following: A. The patient has tried and had an inadequate response to at least ONE generic ophthalmic corticosteroid **OR** B. The patient has an intolerance or hypersensitivity to therapy with generic ophthalmic corticosteroids that is not expected to occur with the requested agent **OR** C. The patient has an FDA labeled contraindication to ALL generic ophthalmic corticosteroids that is not expected to occur with the requested agent **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 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 generic ophthalmic corticosteroids 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 **OR** 2. The patient has been previously treated with the requested agent AND ALL of the following: A. ONE of the following: 1. The patient has tried and had an inadequate response to at least ONE generic ophthalmic corticosteroid **OR** 2. The patient has an intolerance or hypersensitivity to therapy with generic ophthalmic corticosteroids that is not expected to occur with the requested agent **OR** 3. The patient has an FDA labeled contraindication to ALL generic ophthalmic corticosteroids that is not expected to occur with the requested agent **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**

Module	Clinical Criteria for Approval
	C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL generic ophthalmic corticosteroids 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** B. The patient has had clinical benefit with the requested agent **AND** C. The patient's eyes have been examined under magnification (e.g., slit lamp), and the patient's intraocular pressure has been evaluated **OR** B. The patient has another FDA labeled indication for the requested agent **OR** C. The patient has an indication that is supported in compendia for the requested agent and route of administration **AND** 2. The patient will NOT be using the requested agent in combination with Verkazia (cyclosporine) or another target agent in this program (e.g., Cequa, Eysuvis, Miebo, Restasis, Tyrvaya, Vevye, Xiidra) **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS or DrugDex 1 or 2a level of evidence **Length of Approval:** 3 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Initial Evaluation** **Restasis (cyclosporine ophthalmic emulsion)** will be approved when ALL of the following are met: 1. ONE of the following: A. ALL of the following: 1. The patient has a diagnosis of dry eye disease (i.e., dry eye syndrome, keratoconjunctivitis sicca [e.g., Sjögren's Syndrome]) **AND** 2. The patient will NOT be using the requested agent in combination with punctal plug(s) **AND** 3. ONE of the following: A. The patient has previously tried or is currently using aqueous enhancements (e.g., artificial tears, gels, ointments [target agents not included]) **OR** B. The patient has an intolerance or hypersensitivity to aqueous enhancements (e.g., artificial tears, gels, ointments [target agents not included]) **OR** C. The patient has an FDA labeled contraindication to ALL aqueous enhancements **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 the 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 aqueous enhancements cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse

Module	Clinical Criteria for Approval
	reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The patient has another FDA labeled indication for the requested agent **OR** C. The patient has an indication that is supported in compendia for the requested agent and route of administration **AND** 2. The patient will NOT be using the requested agent in combination with Verkazia (cyclosporine) or another target agent in this program (e.g., Cequa, Eysuvis, Miebo, Restasis, Tyrvaya, Vevye, Xiidra) **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS or DrugDex 1 or 2a level of evidence **Length of Approval:** 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient will NOT be using the requested agent in combination with Verkazia (cyclosporine) or another target agent in this program (e.g., Cequa, Eysuvis, Miebo, Restasis, Tyrvaya, Vevye, Xiidra) **AND** 4. If the requested agent is Eysuvis (loteprednol etabonate), the patient's eyes have been examined under magnification (e.g., slit lamp), and the intraocular pressure has been evaluated **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** Eysuvis (loteprednol etabonate) - 3 months, all other agents - 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Universal QL	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 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: A. BOTH of the following: 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. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **OR** C. BOTH of the following: 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

Module	Clinical Criteria for Approval
	Length of Approval: up to 12 months