Lyrica (pregabalin) Savella (milnacipran) Step Therapy with Quantity Limit Program Summary

Step Therapy program applies to FlexRx Open, FlexRx Closed, GenRx Closed, GenRx Open, and Health Insurance Marketplace formularies.

This is a GenRx standard step therapy program.

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

Quantity limits apply to FlexRx Closed, FlexRx Open, FocusRx, GenRx Closed, GenRx Open, Health Insurance Marketplace, and KeyRx.

POLICY REVIEW CYCLE

Effective Date	Date of Origin
07-01-2024	01-01-2017

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
LYRICA® (pregabalin)* Capsule Oral solution	Neuropathic pain associated with diabetic peripheral neuropathy (DPN) Postherpetic neuralgia (PHN) Adjunctive therapy for the treatment of partial-onset seizures in patients 1 month of age and older Fibromyalgia Neuropathic pain associated with spinal cord injury	*generic available	1
LYRICA® CR (pregabalin ER)* Tablet	The management of: • neuropathic pain associated with diabetic peripheral neuropathy (DPN) • postherpetic neuralgia (PHN) Efficacy of LYRICA CR has not been established for the management of fibromyalgia or as adjunctive therapy for adult patients with partial onset seizures.	*generic available	9
Savella® (milnacipran) Tablet Titration pack	Management of fibromyalgia Savella is not approved for use in pediatric patients.		2

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

CLINICAL RATIONALE

Fibromyalgia	Fibromyalgia is a chronic condition with unknown etiology. It is characterized by generalized body pain, fatigue, sleep disturbance, impaired cognition, and anxiety.

	Diagnosis is often made by exclusion of other conditions such as neurological syndromes and depression. There is no clear specific pathophysiological therapeutic target. Various guidelines for treatment exist and they are not in agreement. There has been an increased focus on non-pharmacologic therapies discussed in the guidelines, however, pharmacology remains the mainstay of therapy. Pharmacologic therapy varies, including classical analgesics, antidepressants, and anticonvulsants. Commonly used agents include tricyclic antidepressants (TCAs), pregabalin, gabapentin, serotonin and norepinephrine reuptake inhibitors (SNRI), selective serotonin reuptake inhibitors (SSRI), tramadol, and cyclobenzaprine.(3)
Neuropathic Pain	**Diabetic Peripheral Neuropathy** Diabetic peripheral neuropathy (DPN) develops as a late manifestation of uncontrolled or long-standing diabetes. DPN patients may develop distal symmetric polyneuropathy (DSPN), which is characterized by burning pain, paresthesias, and numbness that follows a stocking-glove pattern and progresses proximally. Poorly controlled blood glucose levels, especially greater variation in glucose levels, contribute to the occurrence and severity of painful DPN.(5) DSPN is the most important cause of foot ulceration and a prerequisite to the development of Charcot neuroarthropathy (CN), which are both recognized as late complications of DSPN. The late complications also drive amputation risk and economic costs of diabetic neuropathy and are also predictors of mortality. DSPN is also a major contributor to falls and fractures.(4) Due to lack of treatments that target the underlying nerve damage, prevention is the key component of diabetes care. Prevention of diabetic neuropathies focuses on glucose control and lifestyle modifications, which includes dietary modifications and exercise. For patients with diabetic neuropathy, foot care is important to prevent ulceration, infection, and amputation.(4) There are several pharmacological options for DPN. The American Diabetes Association (ADA) and American Academy of Family Physicians (AAFP) recommend use of pregabalin and duloxetine as first-line therapy for painful diabetic neuropathy. The ADA recommends gabapentin as the alternative first-line agent, though AAFP considers it a first-line therapy.(4,5) Other treatment options include antidepressants (e.g., amitriptyline, nortriptyline, desipramine, imipramine, venlafaxine), anticonvulsants (e.g. lamotrigine, topiramate, valproate), and topical agents (e.g., capsaicin cream, lidocaine 5% patch).(4,5) Tramadol has been shown to be effective in the treatment of DPN. Although tramadol has a lower potential for abuse compared with other opioids, given the safety concern it is not recommended as first or second-line treatment.(4) **Postherpetic Neuralgia** Postherpetic neuralgia (PHN), the most common complication of herpes zoster, is defined as pain in a dermatomal distribution that is sustained for at least 90 days after the rash. It occurs in approximately 20% of patients with herpes zoster, and 80% of cases occur in patients 50 years or older. PHN is caused by nerve damage secondary to an inflammatory response induced by viral replication within a nerve.(6) Gabapentin, pregabalin, and the TCAs are considered first-line therapies, along with the topical therapies of lidocaine and capsaicin. Tramadol is considered a third-line option.(6) The European consensus guideline on the management of herpes zoster recommends tricyclic antidepressants, gabapentin, or pregabalin for pain relief.(10) **Neuropathic Pain due to Spinal Cord Injury** Spinal cord injury (SCI) is an injury to the spinal cord that leads to varying degrees of motor and/or sensory deficits and paralysis. Chronic neuropathic pain is common and contributes to reduced quality of life. First-line drugs commonly used are amitriptyline, gabapentin, and pregabalin. Alternative agents are tramadol and duloxetine.(7)
Seizure Disorders	The occurrence of a single seizure does not always require initiation of antiepileptic drugs (AEDs). In the absence of risk factors, physicians should consider delaying used

	of AEDs until a second seizure occurs. Treatment should begin with monotherapy.(8) LYRICA has FDA approval for adjunctive therapy for the treatment of partial-onset seizures in patients 1 month of age and older.(1)
Safety	LYRICA and LYRICA CR are contraindicated in patients with a known hypersensitivity to pregabalin or any of its components.(1,9) Savella has the following contraindications:(2) • Do not use MAOIs intended to treat psychiatric disorders with Savella or within 5 days of stopping treatment with Savella • Do not use Savella within 14 days of stopping an MAOI intended to treat psychiatric disorders • Do not start Savella in a patient who is being treated with linezolid or intravenous methylene blue Savella carries a boxed warning for suicidality and antidepressant drugs.(2) • Increased risk of suicidal ideation, thinking, and behavior in children, adolescents, and young adults taking antidepressants for major depressive disorder (MDD) and other psychiatric disorders • Savella is not approved for use in pediatric patients

REFERENCES

Number	Reference
1	LYRICA prescribing information. Parke-Davis Div of Pfizer. June 2020.
2	Savella prescribing information. Allergan, Inc. September 2023.
3	Kia S, Choy E. Update on Treatment Guideline in Fibromyalgia Syndrome with Focus on Pharmacology. *Biomedicines.* 2017;5(2):20. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5489806/
4	Pop-Busui R, Boulton AJM, Feldman EL, et al. Diabetic Neuropathy: A Position Statement by the American Diabetes Association. *Diabetes Care.* 2017;40(1):136-154. https://care.diabetesjournals.org/content/40/1/136.
5	Snyder MJ, Gibbs LM, Lindsay TJ. Treating Painful Diabetic Peripheral Neuropathy: An Update. *Am Fam Physician*. 2016;94(3):227-234. https://www.aafp.org/afp/2016/0801/p227.html.
6	Saguil A, Kane S, Mercado M, Lauters R. Herpes Zoster and Postherpetic Neuralgia: Prevention and Management. *Am Fam Physician* 2017;96(10):656-663. https://www.aafp.org/afp/2017/1115/p656.html.
7	Hagen EM, Rekand T. Management of Neuropathic Pain Associated with Spinal Cord Injury. *Pain Ther* 2015;4(1):51-65. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4470971/#__ffn_sectitle.
8	Liu G, Slater N, Perkins A. Epilepsy: Treatment Options. *American Family Physician.* 2017; 95(2):87-96. https://www.aafp.org/afp/2017/0715/p87.html
9	LYRICA CR prescribing information. Parke-Davis Div of Pfizer. June 2020.
10	Werner RN, Nikkels AF, Marinovic B, et. al. "European consensus-based (S2k) Guideline on the Management of Herpes Zoster - guided by the European Dermatology Forum (EDF) in cooperation with the European Academy of Dermatology and Venereology (EADV), Part 2: Treatment. J*ournal of the European Academy of Dermatology and Venereology*. 2017,31, 20-29. doi: 10.1111/jdv.13957

POLICY AGENT SUMMARY STEP THERAPY

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Lyrica	pregabalin cap ; pregabalin soln	100 MG ; 150 MG ; 20 MG/ML ; 200 MG ; 225 MG ; 25 MG ; 300 MG ; 50 MG ; 75 MG	M ; N ; O	O ; Y		
Lyrica cr	pregabalin tab er	165 MG ; 330 MG ; 82.5 MG	M ; N ; O ; Y	O ; Y		
Savella ; Savella titration pack	milnacipran hcl tab	100 MG ; 12.5 & 25 & 50 MG ; 12.5 MG ; 25 MG ; 50 MG	M ; N ; O	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
Lyrica	Pregabalin Cap 100 MG	100 MG	90	Capsules	30	DAYS			
Lyrica	Pregabalin Cap 150 MG	150 MG	90	Capsules	30	DAYS			
Lyrica	Pregabalin Cap 200 MG	200 MG	90	Capsules	30	DAYS			
Lyrica	Pregabalin Cap 225 MG	225 MG	60	Capsules	30	DAYS			
Lyrica	Pregabalin Cap 25 MG	25 MG	90	Capsules	30	DAYS			
Lyrica	Pregabalin Cap 300 MG	300 MG	60	Capsules	30	DAYS			
Lyrica	Pregabalin Cap 50 MG	50 MG	90	Capsules	30	DAYS			
Lyrica	Pregabalin Cap 75 MG	75 MG	90	Capsules	30	DAYS			
Lyrica	Pregabalin Soln 20 MG/ML	20 MG/ML	900	mLs	30	DAYS			
Lyrica cr	Pregabalin Tab ER 24HR 165 MG	165 MG	30	Tablets	30	DAYS			
Lyrica cr	Pregabalin Tab ER 24HR 330 MG	330 MG	60	Tablets	30	DAYS			
Lyrica cr	Pregabalin Tab ER 24HR 82.5 MG	82.5 MG	30	Tablets	30	DAYS			
Savella	Milnacipran HCl Tab 100 MG	100 MG	60	Tablets	30	DAYS			
Savella	Milnacipran HCl Tab 12.5 MG	12.5 MG	60	Tablets	30	DAYS			
Savella	Milnacipran HCl Tab 25 MG	25 MG	60	Tablets	30	DAYS			
Savella	Milnacipran HCl Tab 50 MG	50 MG	60	Tablets	30	DAYS			
Savella titration pack	Milnacipran HCl Tab 12.5 MG (5) & 25 MG (8) & 50 MG (42) Pak	12.5 & 25 & 50 MG	1	Pack	180	DAYS			

CLIENT SUMMARY – STEP THERAPY

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Lyrica	pregabalin cap ; pregabalin soln	100 MG ; 150 MG ; 20 MG/ML ; 200 MG ; 225 MG ; 25 MG ; 300 MG ; 50 MG ; 75 MG	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx
Lyrica cr	pregabalin tab er	165 MG ; 330 MG ; 82.5 MG	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx
Savella ; Savella titration pack	milnacipran hcl tab	100 MG ; 12.5 & 25 & 50 MG ; 12.5 MG ; 25 MG ; 50 MG	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Lyrica	Pregabalin Cap 100 MG	100 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Lyrica	Pregabalin Cap 150 MG	150 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Lyrica	Pregabalin Cap 200 MG	200 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Lyrica	Pregabalin Cap 225 MG	225 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Lyrica	Pregabalin Cap 25 MG	25 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Lyrica	Pregabalin Cap 300 MG	300 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Lyrica	Pregabalin Cap 50 MG	50 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Lyrica	Pregabalin Cap 75 MG	75 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Lyrica	Pregabalin Soln 20 MG/ML	20 MG/ML	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
Lyrica cr	Pregabalin Tab ER 24HR 165 MG	165 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Lyrica cr	Pregabalin Tab ER 24HR 330 MG	330 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Lyrica cr	Pregabalin Tab ER 24HR 82.5 MG	82.5 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Savella	Milnacipran HCl Tab 100 MG	100 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Savella	Milnacipran HCl Tab 12.5 MG	12.5 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Savella	Milnacipran HCl Tab 25 MG	25 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Savella	Milnacipran HCl Tab 50 MG	50 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Savella titration pack	Milnacipran HCl Tab 12.5 MG (5) & 25 MG (8) & 50 MG (42) Pak	12.5 & 25 & 50 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Lyrica	**TARGET AGENT(S)** **LYRICA** (pregabalin)* * – available as a generic; included as a prerequisite in the step therapy program **LYRICA** will be approved when ONE of the following is met: 1. 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 by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 2. The patient has a diagnosis of a seizure disorder **OR**

Module	Clinical Criteria for Approval
	3. The patient has medication history of use with another anticonvulsant within the past 90 days **OR** 4. The patient has medication history of use with generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin or tramadol **OR** 5. BOTH of the following: A. The prescriber has stated that the patient has tried generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin, or tramadol **AND** B. The prerequisite agent (i.e., generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin, or tramadol) was discontinued due to lack of effectiveness or an adverse event **OR** 6. The patient has an intolerance or hypersensitivity to a prerequisite agent (i.e., generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin, or tramadol) **OR** 7. The patient has an FDA labeled contraindication to ALL prerequisite agents (i.e., generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin, AND tramadol) **OR** 8. The prescriber has provided documentation that ALL prerequisite agents (i.e., generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, AND tramadol) 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 **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Lyrica CR	**TARGET AGENT(S)** **LYRICA CR** (pregabalin ER)* * – available as a generic; included as a target in the step therapy program **Target Agent(s)** will be approved when ONE of the following is met: 1. 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 by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 2. BOTH of the following: A. ONE of the following: 1. BOTH of the following: A. The prescriber has stated that the patient has tried generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, venlafaxine, or gabapentin **AND** B. The prerequisite agent (i.e., generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, venlafaxine, or gabapentin) was discontinued due to lack of effectiveness or an adverse event **OR** 2. The patient has an intolerance or hypersensitivity to a prerequisite agent (i.e., generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, venlafaxine, or gabapentin) **OR** 3. The patient has an FDA labeled contraindication to ALL prerequisite agents (i.e., generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, venlafaxine, AND gabapentin) **OR** 4. The prescriber has provided documentation that ALL prerequisite agents (i.e., generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, venlafaxine, AND gabapentin) 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. ONE of the following: 1. BOTH of the following:

Module	Clinical Criteria for Approval
	A. The prescriber has stated that the patient has tried generic pregabalin immediate release **AND** B. Generic pregabalin immediate release was discontinued due to lack of effectiveness or an adverse event **OR** 2. The patient has an intolerance or hypersensitivity to generic pregabalin immediate release **OR** 3. The patient has an FDA labeled contraindication to generic pregabalin immediate release **OR** 4. The prescriber has provided documentation that generic pregabalin immediate release 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 **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Savella	**TARGET AGENT(S)** **Savella®** (milnacipran) **Savella** will be approved when ONE of the following is met: 1. 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 by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 2. The patient's medication history includes use of generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin, or tramadol **OR** 3. BOTH of the following: A. The prescriber has stated that the patient has tried generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin, or tramadol **AND** B. The prerequisite agent (i.e., generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin, or tramadol) was discontinued due to lack of effectiveness or an adverse event **OR** 4. The patient has an intolerance or hypersensitivity to a prerequisite agent (i.e., generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin, or tramadol) **OR** 5. The patient has an FDA labeled contraindication to ALL prerequisite agents (i.e., generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin, AND tramadol) **OR** 6. The prescriber has provided documentation that ALL prerequisite agents (i.e., generic duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, venlafaxine, gabapentin, pregabalin, AND tramadol) 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 **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	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**

Module	Clinical Criteria for Approval
	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. BOTH of the following: 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: 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 **Length of Approval**: up to 12 months