Baclofen 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
04-01-2024	04-01-2020

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Fleqsuvy® (baclofen) Oral suspension*	Treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscle rigidity May also be of some value in patients with spinal cord injuries and other spinal cord diseases Limitations of Use: Fleqsuvy is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders.	*generic available	6
LYVISPAH® (baclofen) Oral granules	Treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity May also be of some value in patients with spinal cord injuries and other spinal cord diseases Limitations of Use: LYVISPAH is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders.		7
OZOBAX® OZOBAX® DS (baclofen) Oral solution	Treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscle rigidity May also be of some value in patients with spinal cord injuries and other spinal cord diseases Limitations of Use: OZOBAX/OZOBAX DS is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders.		1,8

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

CLINICAL RATIONALE

Multiple Sclerosis	Multiple sclerosis (MS) is a disorder of the central nervous system (CNS) characterized by demyelization, inflammation, and degenerative changes. Most people with MS experience relapses and remissions of neurological symptoms, particularly early in the disease, and clinical events are usually associated with areas of CNS inflammation. Gradual worsening or progression, with or without subsequent acute attacks of inflammation or radiological activity, may take place early, but usually becomes more prominent over time. While traditionally viewed as a disease solely of CNS white

	matter, more advanced imaging techniques have demonstrated significant early and ongoing CNS gray matter damage as well.(2) Those diagnosed with MS may have many fluctuating and disabling symptoms (including, but not limited to, fatigue, impaired mobility, mood and cognitive changes, pain and other sensory problems, visual disturbances, and elimination dysfunction), resulting in a significant impact on quality of life for patients and their families. There are currently four major types of MS: clinically isolated syndrome (CIS), relapsing-remitting MS (RRMS), primary progressive MS (PPMS), and secondary progressive MS (SPMS).(2) Spasticity from the upper motor neuron syndrome (a complex of signs and symptoms that can be associated with exaggerated reflexes, autonomic hyperreflexia, dystonia, contractures, paresis, lack of dexterity, and fatigability, in addition to spasticity) can result from a variety of conditions affecting the cortex or spinal cord. Some of the more common conditions associated with spasticity include multiple sclerosis, spinal cord injury, traumatic brain injury, cerebral palsy, and post-stroke syndrome. In many patients with these conditions, spasticity can be disabling and painful, with a marked effect on functional ability and quality of life. Baclofen, dantrolene, and tizanidine are approved for the treatment of spasticity related to multiple sclerosis. Other medications used to treat spasticity with multiple sclerosis include benzodiazepines, clonidine, and gabapentin.(3) There is evidence that baclofen, tizanidine, and dantrolene are effective compared to placebo in patients with spasticity related to multiple sclerosis. Baclofen and tizanidine are roughly equivalent for efficacy in patients with spasticity. The overall rate of adverse effects between baclofen and tizanidine is similar, tizanidine causes more dry mouth and baclofen more weakness.(3)
Spinal Cord Injury	A spinal cord injury (SCI) is a traumatic event that results in a disturbance to normal sensory, motor, or autonomic function and can significantly impair a patient's quality of life, functional status, and social independence. Motor vehicle accidents are the primary cause of SCI, followed by falls in the elderly population.(9) Immobility and spasticity contribute to muscle contractures after SCI. Preventive management is extremely important and should begin immediately after an SCI and continue for long-term. Preventative management includes positioning, range-of-motion exercises, and splinting.(5) Baclofen, dantrolene, pregabalin and tizanidine are approved for spasticity with spinal cord injuries. Methylprednisolone can be used for SCI but the Congress of Neurological Surgeons states there is insufficient evidence to make a recommendation.(4)
Efficacy	The efficacy of Fleqsuvy (baclofen), LYVISPAH (baclofen), and OZOBAX/OZOBAX DS (baclofen) is based on bioavailability studies in healthy adults comparing baclofen oral tablets to Fleqsuvy, LYVISPAH, or OZOBAX/OZOBAX DS.(1,6,7,8)
Safety	Abrupt discontinuation of baclofen, regardless of the cause, has resulted in adverse reactions that include hallucinations, seizures, high fever, altered mental status, exaggerated rebound spasticity, and muscle rigidity, that in rare cases has advanced to rhabdomyolysis, multiple organ-system failure, and death. Therefore, reduce the dosage slowly when discontinuing, unless the clinical situation justifies a rapid withdrawal.(1,6,7,8) Fleqsuvy, LYVISPAH, and OZOBAX/OZOBAX DS are contraindicated in patients with hypersensitivity to baclofen.(1,6,7,8)

REFERENCES

Number	Reference
1	OZOBAX Prescribing Information. Metacel Pharmaceuticals, LLC. May 2020.
2	Multiple Sclerosis Coalition. The Use of Disease Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. A Consensus Paper by the Multiple Sclerosis Coalition. Original July 2014. Updated September 2019.

Number	Reference
3	Chou R, Peterson K, Helfand M. Comparative Efficacy and Safety of Skeletal Muscle Relaxants for Spasticity and Musculoskeletal Conditions: A Systemic Review. *Journal of Pain and Symptom Management*. 2004 Aug;28(2):140-75.
4	Arnold PM, Anderson PA, Chi JH, et al. Congress of Neurological Surgeons Systematic Review and Evidence-Based Guidelines on the Evaluation and Treatment of Patients with Thoracolumbar Spine Trauma: Pharmacological Treatment. *Neurosurgery.* 2019 Jan;84(1):E36-E38.
5	Dalyan M, Sherman A, Cardenas DD. Factors associated with contractures in acute spinal cord injury. *Spinal Cord.* 1998 Jun;36(6):405-8.
6	Fleqsuvy Prescribing Information. Azurity Pharmaceuticals, Inc. February 2023.
7	LYVISPAH prescribing information. Amneal Pharmaceuticals LLC. April 2023.
8	OZOBAX DS Prescribing Information. Metacel Pharmaceuticals, LLC. October 2023.
9	Fehlings MG, Tetreault LA, Wilson JR, Kwon BK, Burns AS, Martin AR, Hawryluk G, Harrop JS. (2017). A Clinical Practice Guideline for the Management of Acute Spinal Cord Injury: Introduction, Rationale, and Scope. Global spine journal, 7(3 Suppl), 84S-94S. https://doi.org/10.1177/2192568217703387

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Lyvispah	baclofen granules packet	10 MG ; 20 MG ; 5 MG	M ; N ; O ; Y	N		
Ozobax ds	baclofen oral soln	10 MG/5ML	M ; N ; O ; Y	M		
Ozobax	Baclofen Oral Soln 5 MG/5ML	5 MG/5ML	M ; N ; O ; Y	M ; N		
Fleqsuvy	Baclofen Susp	25 MG/5ML	M ; N ; O ; Y	O ; Y		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Fleqsuvy	Baclofen Susp	25 MG/5ML	480	mLs	30	DAYS			
Lyvispah	Baclofen Granules Packet	5 MG	120	Packets	30	DAYS			
Lyvispah	Baclofen Granules Packet	10 MG	120	Packets	30	DAYS			
Lyvispah	Baclofen Granules Packet	20 MG	120	Packets	30	DAYS			
Ozobax	Baclofen Oral Soln 5 MG/5ML	5 MG/5ML	2400	mLs	30	DAYS			
Ozobax ds	baclofen oral soln	10 MG/5ML	1200	mLs	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Fleqsuvy	Baclofen Susp	25 MG/5ML	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Lyvispah	baclofen granules packet	10 MG ; 20 MG ; 5 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Ozobax	Baclofen Oral Soln 5 MG/5ML	5 MG/5ML	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Ozobax ds	baclofen oral soln	10 MG/5ML	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
Fleqsuvy	Baclofen Susp	25 MG/5ML	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Lyvispah	Baclofen Granules Packet	10 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Lyvispah	Baclofen Granules Packet	5 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Lyvispah	Baclofen Granules Packet	20 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Ozobax	Baclofen Oral Soln 5 MG/5ML	5 MG/5ML	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Ozobax ds	baclofen oral soln	10 MG/5ML	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
	Initial Evaluation **Target Agent(s)** will be approved when BOTH of the following are met: 1. ONE of the following: A. The patient has a diagnosis of spasticity resulting from multiple sclerosis (MS) AND BOTH of the following: 1. The requested agent will be used for at least ONE of the following: A. Flexor spasms and concomitant pain **OR** B. Clonus **OR** C. Muscular rigidity **AND** 2. ONE of the following: A. BOTH of the following: 1. ONE of the following: A. The patient has an intolerance or hypersensitivity to generic baclofen tablets that is not expected to occur with the requested agent **OR** B. The patient has an FDA labeled contraindication to generic baclofen tablets that is not expected to occur with the requested agent **OR** C. The prescriber has provided information to support use of the requested agent over generic baclofen tablets **OR** D. BOTH of the following: 1. The prescriber has stated that the patient has tried to generic baclofen tablets **AND** 2. Generic baclofen tablets were 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: 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 generic baclofen tablets 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 another muscle relaxant (e.g., dantrolene, tizanidine) used for spasticity related to multiple sclerosis **OR** B. The patient has an intolerance or hypersensitivity to ALL muscle relaxants used for spasticity related to multiple sclerosis **OR**

Module	Clinical Criteria for Approval
	C. The patient has an FDA labeled contraindication to ALL muscle relaxants used for spasticity related to multiple sclerosis **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 muscle relaxants used for spasticity related to multiple sclerosis 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 prescriber has provided information on why the patient is unable to use a solid dosage form (e.g., difficulty swallowing tablets or capsules, feeding tube) **OR** B. The patient has a diagnosis of spasticity related to spinal cord injury or other spinal cord disease AND ONE of the following: 1. BOTH of the following: A. ONE of the following: 1. The patient has an intolerance or hypersensitivity to generic baclofen tablets that is not expected to occur with the requested agent **OR** 2. The patient has an FDA labeled contraindication to generic baclofen tablets that is not expected to occur with the requested agent **OR** 3. The prescriber has provided information to support use of the requested agent over generic baclofen tablets **OR** 4. BOTH of the following: A. The prescriber has stated that the patient has tried to generic baclofen tablets **AND** B. Generic baclofen tablets were discontinued due to lack of effectiveness or an adverse event **OR** 5. 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** 6. The prescriber has provided documentation that generic baclofen tablets cannot be used due to a documented

Module	Clinical Criteria for Approval
	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. The patient has tried and had an inadequate response another muscle relaxant (e.g., dantrolene, pregabalin, tizanidine) used for spasticity related to spinal cord injuries or other spinal diseases **OR** 2. The patient has an intolerance, or hypersensitivity to ALL muscle relaxants used for spasticity related to spinal cord injuries or other spinal cord diseases **OR** 3. The patient has an FDA labeled contraindication to ALL muscle relaxants used for spasticity related to spinal cord injuries or other spinal cord diseases **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 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** 5. The prescriber has provided documentation that ALL muscle relaxants used for spasticity related to spinal cord injuries or other spinal cord diseases 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 prescriber has provided information on why the patient is unable to use a solid dosage form (e.g., difficulty swallowing tablets or capsules, feeding tube) **AND** 2. The patient does NOT have any FDA labeled contraindications to the requested agent **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 **AND** 2. The patient has had clinical benefit with the requested agent (e.g., decreased spasms) **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months

Module	Clinical Criteria for Approval
	NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**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. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **Length of Approval:** Initial: 6 months, Renewal:12 months