

PRIOR AUTHORIZATION CRITERIA

BRAND NAME (generic)

FLEQSUVY
(baclofen suspension)

LYVISPAH
(baclofen oral granules)

OZOBAX
(baclofen solution)

OZOBAX DS
(baclofen solution)

Status: CVS Caremark® Criteria

Type: Initial Prior Authorization with Quantity Limit

POLICY

FDA-APPROVED INDICATIONS

Fleqsuvy

Fleqsuvy is indicated for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. Fleqsuvy 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.

Lyvispah

Lyvispah is indicated for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. Lyvispah may also be of some value in patients with spinal cord injuries and other spinal cord diseases.

Limitation of Use

Lyvispah is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders.

Ozobax

Ozobax is indicated for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. Ozobax may also be of some value in patients with spinal cord injuries and other spinal cord diseases.

Limitations of Use

Ozobax is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders.

Ozobax DS

Ozobax DS is indicated for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity.

Ozobax DS may also be of some value in patients with spinal cord injuries and other spinal cord diseases.

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Limitations of Use

Ozobax DS is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for the treatment of spasticity resulting from ANY of the following: A) multiple sclerosis, B) a spinal cord injury, C) a spinal cord disease (e.g., including but not limited to transverse myelitis, neuromyelitis optica spectrum disorder [NMOSD], myelin oligodendrocyte glycoprotein antibody disease [MOGAD])
AND
 - The patient has difficulty swallowing tablets**OR**
 - The request is for Lyvispah (baclofen oral granules)**AND**
 - The patient requires administration of the requested drug via enteral feeding tube

Quantity Limits apply.

<u>QUANTITY LIMIT</u>		
Drug	1 Month Limit*	3 Month Limit*
Fleqsuvy 25 mg/5 mL (5 mg/mL) Oral Suspension (baclofen suspension)	480 mL / 25 days	1,440 mL / 75 days
Lyvispah 5 mg Oral Granules Single Dose Packets (baclofen oral granules)	120 packets / 25 days	360 packets / 75 days
Lyvispah 10 mg Oral Granules Single Dose Packets (baclofen oral granules)	120 packets / 25 days	360 packets / 75 days
Lyvispah 20 mg Oral Granules Single Dose Packets (baclofen oral granules)	120 packets / 25 days	360 packets / 75 days
Ozobax 5 mg/5 mL Oral Solution (baclofen solution)	2,400 mL / 25 days	7,200 mL / 75 days
Ozobax DS 10 mg/ 5mL Oral Solution (baclofen solution)	1,200 mL / 25 days	3,600 mL / 75 days
<i>*The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.</i>		

Duration of Approval (DOA):

- 3401-C: DOA: 36 months

REFERENCES

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2. Fleqsuvy [package insert]. Woburn, MA: Azurity Pharmaceuticals, Inc.; February 2023.
3. Lyvispah [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; April 2023.
4. Ozobax [package insert]. Athens, GA: Metacel Pharmaceuticals, LLC; May 2020.
5. Ozobax DS [package insert]. Athens, GA: Metacel Pharmaceuticals, LLC; October 2023.
6. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. <https://online.lexi.com>. Accessed July 11, 2023.
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9. Logemann JA, Burnham A. Swallowing Disorders and Their Management in Patients with MS. National Multiple Sclerosis Society. 2018. Available at: <https://nms2cdn.azureedge.net/cmssite/nationalmssociety/media/msnationalfiles/brochures/clinical-bulletin-swallowing-disorders-and-their-management.pdf>. Accessed July 11, 2023.