Date:

Payer Company Name

Street/Building Address

City, State ZIP

ATTN: Contact Name/ Contact Title

Re: Letter of LYVISPAH Medical Necessity for Plan Member Name

*Plan member information:*

Name: First and Last Name

Date of Birth: MM/DD/YYYY

ID Number: Insurance ID Number

Group Number: Insurance Group Number

Dear Sir or Madam:

This letter is to explain the rationale for my prescription of baclofen oral granules (LYVISPAHTM) for patient name. This individual suffers from spasticity resulting from Multiple sclerosis, spinal cord injury, and/or other spinal cord disease.

LYVISPAH has been FDA approved since December 2021 and is bioequivalent to oral baclofen tablets.1,2 It is also well recognized by experts that baclofen is an effective drug treatment for spasticity. Baclofen results in alleviation of signs and symptoms of spasticity, particularly relief of flexor spasms and concomitant pain, clonus, and muscular rigidity.3

Currently, there are 4 forms of oral baclofen on the US market, all of which have been FDA approved for use in spasticity resulting from Multiple sclerosis, spinal cord disease, and/or other spinal cord disease. These include generic baclofen tablets, LYVISPAH (baclofen oral granules), Fleqsuvy (baclofen oral suspension)4, and Ozobax (baclofen oral solution)5.While all 4 products consist of the same active ingredient (baclofen), they differ in their dosage formulations and indicated routes of administration.

LYVISPAH helps those patients with dysphagia and/or using a feeding tube by providing a baclofen formulation that provides accurate dosing and can be administered in multiple ways. Patients can administer LYVISPAH in multiple ways: pouring directly in their mouth, dissolving in liquids or soft food, or via enteral feeding tubes. LYVISPAH does not need to be shaken or reconstituted and can be stored at room temperature, ensuring consistent and accurate dosing.

LYVISPAH helps patients (and their caregivers) deliver accurate dosing. Crushing baclofen tablets may be a difficult task for patients and/or caregivers and can increase the risk for inadequate or inaccurate dosing. Studies with various crushing methods have shown drug loss ranging from 0 – 38%. Drug loss should not be above the threshold of <3% set by the FDA.6 Steps to recover the lost drug are inconvenient and time-consuming for nurses, caregivers, and patients and may still result in drug loss above the FDA threshold.7

In my opinion, Lyvispah would be the most appropriate treatment option to meet the unique needs for my patient.

In light of the foregoing considerations, it is essential that you approve LYVISPAH for my patient. It is my view that use of other preparations of baclofen create challenges for my patient and/or their caregivers and LYVISPAH provides a needed solution for my patient’s needs.

Sincerely,

Signature line

**References**: 1. Saol Therapeutics. (2021, December 6). Saol Therapeutics Announces FDA Approval of LYVISPAHTM (baclofen) Oral Granules and the Divesture of its Plasma-derived Hyperimmune Portfolio [Press release]. <https://saolrx.com/saol-therapeutics-announces-fda-approval-of-lyvispahtm-baclofen-oral-granules-and-the-divesture-of-its-plasma-derived-hyperimmune-portfolio/>**2.** LYVISPAH (baclofen) oral granules [package insert]. Roswell, GA: Saol Therapeutics; 2021. **3.** Ghanavatian S, Derian A. Baclofen [Updated 2021 Dec 17]. In: StatPearls [Internet] Treasure Island (FL): StatPearls Publishing; 2022 Jan. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK526037>. **4.** FLEQSUVY [package insert]. Wilmington, MA: Azurity Pharmaceuticals, Inc; 2021. **5.** OZOBAX [prescribing information]. Athens, GA: Metacel Pharmaceuticals, LLC; 2019. **6.** Betul Tosun, Nursemin Unal, Nurten Ozen, Filiz Atalay; Comparison of Dosage Loss Between Medications Crushed with Two Different Methods by Two Nurses: An Invitro Study. *Bezmialem Science*. 2021;9(1):106-11. **7.** Min Yew Thong, Yady J. Manrique, Kathryn J. Steadman; Drug loss while crushing tablets: Comparison of 24 tablet crushing devices. *PLoS ONE* 13(3):e0193683.