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 and is currently using a type of feeding tube.

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 the treatment of spasticity. This drug 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 is the only oral baclofen formulation that is approved for administration via feeding tube**.2 LYVISPAH can be administered via enteral feeding tubes such as nasogastric (NG) at sizes 8 FR or higher, gastrostomy (G) at sizes 12 FR or higher, percutaneous endoscopic gastrostomy (PEG) at sizes 14 FR or higher, and gastrojejunostomy (GJ) tubes at sizes 16 FR or higher.

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.