To whom it may concern:

I am contacting you as a dermatologist caring for @M@ @LNAME@ with regard to the patient's diagnosis of Bullous Pemphigoid.

This letter is to document the medical necessity of IVIg for @M@ @LNAME@.

As you know, bullous pemphigoid is an extremely morbid condition that causes severe blistering and painful erosions in the skin and mucous membranes. Left untreated, it can lead to hospitalization and death. There are NO FDA-approved medications for this condition.

When treating a patient with Bullous Pemphigoid, it is necessary to have access to the full spectrum of accepted treatments as patients may not be able to use one particular treatment due to lack of response, the potential for side effects or even an allergic reaction. It can become a serious safety issue for the patient if I am not able to prescribe a wide variety of treatments for this condition.

I strongly believe @M@ @LNAME@ needs access to IVIg. My patient has previously tried and failed ***. IVIg has been shown to have benefit in patients with bullous pemphigoid and is included in expert guidelines (see references below).

My patient is not a good candidate for other alternatives used to treat bullous pemphigoid for the following reasons:

Topical corticosteroids: The patient has already used topical corticosteroids which have not been adequately effective. Moreover, bullous pemphigoid is a chronic condition, and overuse of corticosteroids will lead to side effects such as striae, cutaneous atrophy, perioral dermatitis, cataracts, glaucoma, and numerous other undesirable adverse effects.

Systemic corticosteroids: My patient has already used systemic corticosteroids and these are not a good long-term option for this patient. With long-term use, systemic corticosteroids have numerous side effects including diabetes, hypertension, osteoporosis, aseptic necrosis of the hip, infection and many other adverse effects. Additionally, my patient has been on prednisone recently without control of his disease.

Methotrexate: Methotrexate is not approved for the treatment of bullous pemphigoid. Moreover, it is associated with life-threatening bone marrow suppression, liver toxicity, and numerous additional adverse effects. Relative contraindications include alcohol consumption, obesity, diabetes, any liver disease, abnormalities in renal function, concomitant use of hepatotoxic drugs or drugs that interact with methotrexate, ongoing infectious diseases, anemia, leukopenia or thrombocytopenia.

Azathioprine (Imuran): Azathioprine is not approved for the treatment of bullous pemphigoid, and is associated with bone marrow toxicity that can be life-threatening.

I also invite you to review the literature that discusses the use of IVIg in bullous pemphigoid below:

1. Borradori L, Van Beek N, Feliciani C, Tedbirt B, Antiga E, Bergman R, Böckle BC, Caproni M, Caux F, Chandran NS, Cianchini G, Daneshpazhooh M, De D, Didona D, Di Zenzo GM, Dmochowski M, Drenovska K, Ehrchen J, Goebeler M, Groves R, Günther C, Horvath B, Hertl M, Hofmann S, Ioannides D, Itzlinger-Monshi B, Jedličková J, Kowalewski C, Kridin K, Lim YL, Marinovic B, Marzano AV, Mascaro JM, Meijer JM, Murrell D, Patsatsi K, Pincelli C, Prost C, Rappersberger K, Sárdy M, Setterfield J, Shahid M, Sprecher E, Tasanen K, Uzun S, Vassileva S, Vestergaard K, Vorobyev A, Vujic I, Wang G, Wozniak K, Yayli S, Zambruno G, Zillikens D, Schmidt E, Joly P. Updated S2 K guidelines for the management of bullous pemphigoid initiated by the European Academy of Dermatology and Venereology (EADV). J Eur Acad Dermatol Venereol. 2022 Oct;36(10):1689-1704. doi: 10.1111/jdv.18220. Epub 2022 Jun 29. PMID: 35766904.
2. Amagai M, Ikeda S, Hashimoto T, Mizuashi M, Fujisawa A, Ihn H, Matsuzaki Y, Ohtsuka M, Fujiwara H, Furuta J, Tago O, Yamagami J, Tanikawa A, Uhara H, Morita A, Nakanishi G, Tani M, Aoyama Y, Makino E, Muto M, Manabe M, Konno T, Murata S, Izaki S, Watanabe H, Yamaguchi Y, Matsukura S, Seishima M, Habe K, Yoshida Y, Kaneko S, Shindo H, Nakajima K, Kanekura T, Takahashi K, Kitajima Y, Hashimoto K; Bullous Pemphigoid Study Group. A randomized double-blind trial of intravenous immunoglobulin for bullous pemphigoid. J Dermatol Sci. 2017 Feb;85(2):77-84. doi: 10.1016/j.jdermsci.2016.11.003. Epub 2016 Nov 9. PMID: 27876358.
3. Ujiie H, Arakawa M, Aoyama Y. Intravenous immunoglobulin in patients with bullous pemphigoid insufficient response to corticosteroids: Nationwide post-marketing surveillance in Japan. J Dermatol Sci. 2023 Jan;109(1):22-29. doi: 10.1016/j.jdermsci.2023.01.004. Epub 2023 Jan 12. PMID: 36697305.

On behalf of @M@ @LNAME@, I would appreciate your prompt reconsideration of this denial. Please feel free to contact me below for any additional information you may require. I look forward to receiving your response and approval of coverage for this medication.

Sincerely,