To Whom It May Concern,

I am writing this letter of medical necessity regarding the administration of Obinutuzumab (Gazyva) for my patient @NAME@. @M@ @LNAME@ is a @AGE@ @SEX@ diagnosed with pemphigus vulgaris. I have determined that it is medically necessary for this patient to receive treatment with obinutuzumab for the reason(s) stated below:

Pemphigus vulgaris (PV) is a severe chronic autoimmune blistering disease that affects the skin and mucous membranes. PV has a progressive course, with loss of body fluids and proteins, and secondary infections, which may lead to sepsis and cardiac failure (Altman, 2020). My patient first developed symptoms of pemphigus vulgaris in ***. @HE@ was started on oral prednisone and had @HIS@ first rituximab infusion in ***. @HE@ had four cycles of rituximab which did well to improve @HIS@ symptoms, but caused @HIM@ to have some adverse effects consistent with allergic reaction to the rituximab (severe pruritus, rash, eosinophilia). Due to the potential outcomes if @HE@ stops treatment @FNAME@ must continue being treated, but @HIS@ reactions to rituximab make continued use inadvisable.

Obinutuzumab is a type II mAB that shows a stronger adhesion and induction of direct cell death, but with minimal complement-dependent cytotoxic response (Altman, 2020). Obinutuzumab/ GA-101 has been designed with a higher affinity to the FcgRIIIa receptor on immune effector cells and therefore has higher ADCC (antibody-dependent cell-mediated cytotoxicity) activity (Huang et al., 2016). Though obinutuzumab has not yet been fully studied in pemphigus vulgaris it works similarly to rituximab but without many of the side effects that rituximab has. In studies with chronic lymphocytic leukemia it showed superior response rates and prolonged progression-free survival compared to chlorambucil monotherapy or rituximab-chlorambucil therapy (Huang et al., 2016). The lower chance of side effects and higher response rate for patients to Obinutuzumab makes it a reasonable second line treatment option.

I have included medical records pertaining to the patient's medical history, current condition, and treatment plan.

Literature attached are the following:

1. Altman, E. M. (2020). Novel therapies for pemphigus vulgaris. American Journal of Clinical Dermatology, 21(6), 765-782.

2. Huang, A., Madan, R. K., & Levitt, J. (2016). Future therapies for pemphigus vulgaris: Rituximab and beyond. Journal of the American Academy of Dermatology, 74(4), 746–753. https://doi.org/10.1016/j.jaad.2015.11.008

I firmly believe that this therapy is clinically appropriate and medically necessary for @NAME@ and @HIS@ health and disease status would benefit if allowed the opportunity to receive this treatment. Please contact me at Dept: *** if you require additional information to ensure the prompt approval for coverage.