**SAMPLE LETTER OF MEDICAL NECESSITY**

***Please Note: This letter is intended as an example for your consideration and may not include all the information necessary to support your prior authorization request. Requirements will vary based on the health plan guidelines and patient benefit design. Please note the requesting provider is entirely responsible for ensuring the accuracy, adequacy, medical necessity, and supportability of all information required. Further, the requesting provider is solely responsible for submission to and follow-up with the health plan regarding this prior authorization request. Use of this document does not guarantee coverage or reimbursement and is not intended to be a substitute for or an influence on the independent medical judgment of the physician.***

[PRESCRIBER LETTERHEAD]

(Date)

(Payer name)

ATTN: PRIOR AUTHORIZATION

(Type in payer name)

(Type in payer address)

**Patient:** (Type in patient’s first and last name)

**Subscriber ID#**: (Type in insurance ID#)

**Subscriber Group #**: (Type in insurance group#)

**Re:** Poteligeo® (mogamulizumab) injection for IV infusion

To whom it may concern:

I am submitting this letter to document the medical necessity of Poteligeo (mogamulizumab) for my patient, [patient name] [policy number] for the treatment of [mycosis fungoides / Sézary syndrome].

On August 8, 2018**,** the FDA approved the use of Poteligeo for the treatment of adult patients with relapsed or refractory mycosis fungoides or Sézary syndrome after at least one prior systemic therapy. The approval was based on results of an open-label,multicenter, international randomized Phase 3 study, which demonstrated a significant improvement in progression-free survival and overall response rate with mogamulizumab compared to an FDA-approved active comparator, vorinostat.

The most common adverse reactions associated with Poteligeo (reported in >20% of patients) were rash, infusion-related reactions, fatigue, diarrhea, musculoskeletal pain, and upper respiratory tract infection. Please see additional safety information and full Prescribing Information at Poteligeo.com.

Please see the enclosed documentation demonstrating the medical necessity of Poteligeo for my patient, (type in patient name). (He/she) has stage [(IB- IV) mycosis fungoides (MF) / Sézary syndrome (SS)], a form of Cutaneous T-Cell Lymphoma (CTCL) requiring systemic therapy. I would appreciate prompt review of this information for authorization of Poteligeo.

**Patient’s Clinical History**

[Patient’s name] is a [age] year old [male/female] who was diagnosed in [date] with [stage of

disease] [MF/SS]. Systemic treatment options for patients with [MF/SS] are limited.

[He/She] underwent [describe treatment to date].

􀀀 [Be sure to include diagnosis and dates]

􀀀 [Past treatments]

􀀀 [Test results that indicate failure of past treatment]

􀀀 [Social & family information (especially if young patient)]

[i.e. young children or grandchildren, contributes to the well-being of the family, part-time

work, volunteer work]

**Treatment Rationale**

Poteligeo was FDA approved on August 8, 2018 for the treatment of adult patients with relapsed it refractory MF and SS after at least one prior systemic treatment. Poteligeo is listed in [list any clinical practice guidelines that recommend Poteligeo]. Poteligeo is given as 1.0 mg/kg over 1 h infusion every week for 5 weeks then every other week until disease progression or unacceptable toxicity**.**

**Summary**

In summary, Poteligeo is medically necessary and reasonable for [Patient Name’s] medical condition. Please contact me if any additional information is required to ensure the prompt

approval of this course of treatment. Should you have any questions, please do not hesitate to

call me at [phone number [MD phone#]

Thank you for your time and consideration.

Sincerely,

(Physician’s name and credentials)

Suggested Enclosures

USPI

Relevant clinical/chart notes