**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:** Medical Necessity request forPoteligeo® (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].

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 on [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]

**Treatment Rationale**

Poteligeo was FDA approved on August 8, 2018 for the treatment of adult patients with relapsed/ 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**.**

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 below for additional important Safety information and visit [www.poteligeohcp.com](http://www.poteligeohcp.com) for the full Prescribing Information.

**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

**INDICATION**

POTELIGEO® (mogamulizumab-kpkc) injection for intravenous infusion is indicated for the treatment of adult patients with relapsed or refractory mycosis fungoides (MF) or Sézary syndrome (SS) after at least one prior systemic therapy.

**IMPORTANT SAFETY INFORMATION**

**Warnings and Precautions**

* **Dermatologic toxicity:** Monitor patients for rash throughout the course of treatment. For patients who experienced dermatologic toxicity in Trial 1, the median time to onset was 15 weeks, with 25% of cases occurring after 31 weeks. Interrupt POTELIGEO for moderate or severe rash (Grades 2 or 3). Permanently discontinue POTELIGEO for life-threatening (Grade 4) rash or for any Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN).
* **Infusion reactions:** Most infusion reactions occur during or shortly after the first infusion. Infusion reactions can also occur with subsequent infusions. Monitor patients closely for signs and symptoms of infusion reactions and interrupt the infusion for any grade reaction and treat promptly. Permanently discontinue POTELIGEO for any life-threatening (Grade 4) infusion reaction.
* **Infections:** Monitor patients for signs and symptoms of infection and treat promptly.
* **Autoimmune complications:** Interrupt or permanently discontinue POTELIGEO as appropriate for suspected immune-mediated adverse reactions. Consider the benefit/risk of POTELIGEO in patients with a history of autoimmune disease.
* **Complications of allogeneic HSCT after POTELIGEO:** Increased risks of transplant complications have been reported in patients who received allogeneic HSCT after POTELIGEO. Follow patients closely for early evidence of transplant-related complications.

**Adverse Reactions**

* **The most common adverse reactions** (reported in ≥10% of patients) with POTELIGEO in the clinical trial were rash, including drug eruption (35%), infusion reaction (33%), fatigue (31%), diarrhea (28%), drug eruption (24%), upper respiratory tract infection (22%), musculoskeletal pain (22%), skin infection (19%), pyrexia (17%), edema (16%), nausea (16%), headache (14%), thrombocytopenia (14%), constipation (13%), anemia (12%), mucositis (12%), cough (11%), and hypertension (10%).

You are encouraged to report suspected adverse reactions to Kyowa Kirin, Inc. at 1-844-768-3544 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.