Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

# Mogamulizumab - Relapsed or Refractory Mycosis Fungoides or Sezary Syndrome

(This form should be completed before the first dose is dispensed.)

## 1. Patient Profile

* Surname: .....

* Given Name: .....

* OHIN: ..... * Chart Number: .....

* Postal Code: .....

* Height (cm): ..... * Weight (kg): ..... * BSA ($m^2$): .....

* Gender: ○ Male ○ Female ○ Other

* Date of Birth: ..... ..... .....
Day Month Year

* Site:

* Attending Physician (MRP- Most Responsible Physician): .....

Requested Prior Approval ☐ Yes * Patient on Clinical Trial ○ Yes ○ No

Other (specify): .....

Specify Arm:
○ Standard of care arm ○ Experimental arm
○ Blinded / Unknown

## Prior Approval Request

* Select the appropriate prior approval scenario:

○ 1-Unknown primary (submit pathology report and clinic note)
○ 2-Clinical document review (identify the patient history that needs to be reviewed against eligibility criteria in Additional Comments below)
○ 3-Regimen modification - schedule (complete questions a and b)
○ 4-Regimen modification - drug substitutions (complete questions a and c)
○ 5-Withholding a drug in combination therapy from start of treatment (complete questions d, e and f)
○ 6-Maintenance therapy delay (submit clinic note)
○ 7-Prior systemic therapy clinical trials (complete question g)
○ 8-Modification due to supply interruption/drug shortage
○ Other (specify)

.....

**All relevant supporting documentation must be submitted at the time of prior approval. Documentation may include a pathology report, clinic note, and/or CT scans.**

a. Co-morbidities / toxicity / justification:

b. Intended regimen schedule:

c. Intended regimen:

d. Drug(s) to be held:

e. Rationale for holding drug(s):

f. Intention to introduce drug at a later date? ☐ Yes

g. Prior clinical trial identifier (e.g., NCT ID, trial name) and treatment description (e.g., arm, drug/regimen):

h. Anticipated date of first treatment: Day Month Year

i. Additional comments:

## 2. Eligibility Criteria

Mogamulizumab is used for the treatment of adult patients with relapsed or refractory histologically confirmed mycosis fungoides (MF) or Sezary syndrome (SS) [stage IB to IV] who have failed at least 1 prior course of systemic therapy and have a good performance status. ☐ Yes

Treatment with mogamulizumab should not be used in patients with active or untreated central nervous system metastases.

## 3. Baseline Information

a. ECOG Performance Status at the time of enrolment ○ 0 ○ 1 ○ 2

* b. Cutaneous T-cell lymphoma subtype
○ Mycosis fungoides
○ Sezary syndrome

* c. Please select the prior systemic therapy/therapies received for MF/SS (check all that apply)
☐ Alemtuzumab ☐ Bexarotene
☐ Brentuximab vedotin
☐ Conventional chemotherapy (monotherapy or multi-agent)
☐ Interferons ☐ Pralatrexate ☐ Romidepsin
☐ Vorinostat ☐ Other

If the patient additionally received other systemic therapy, please specify

d. Is the patient transitioning from a private pay or compassionate program? ○ Yes ○ No

e. If yes, please indicate the funding source ○ Private payer ○ Manufacturer patient support program

f. If yes, please indicate the date of the last administered dose _____ Day _____ Month _____ Year

## 4. Funded Dose

Mogamulizumab 1 mg/kg intravenously (IV) on days 1, 8, 15, and 22 of the first 28-day cycle, and then on days 1 and 15 of each subsequent 28-day cycle.

Treatment should continue until disease progression or unacceptable toxicity, whichever comes first.

Patients with a global complete response (CR) could continue treatment for up to 12 months or until disease progression, whichever comes first.

[ST-QBP regimen code(s): MOGA]

## 5. Notes

1. Patients with stage IA MF are not eligible.

2. Patients with large cell transformation of MF/SS are eligible for funding of mogamulizumab provided all other eligibility criteria are met.

## 6. FAQs

1. **My patient is currently receiving mogamulizumab through non-publicly funded means (e.g., patient support program, private insurance). Can my patient be transitioned to receive funding through the New Drug Funding Program (NDFP)?**

   Provided the eligibility criteria were met at the time of treatment initiation and the patient's disease has not progressed, your patient may be eligible for continued coverage of mogamulizumab through the NDFP.

2. **What is the process for transitioning my patient from a non-publicly funded program to NDFP funding?**

   If your patient meets all of the eligibility criteria outlined in this policy, please submit as a regular eClaims enrolment.

   Prior approval requests are reserved for instances where there is clinical uncertainty on eligibility. In these circumstances, please specify your reason(s) for uncertainty and upload the following:
   - A clinic note and imaging (if applicable) from treatment initiation, AND
   - The most recent clinic note and imaging (if applicable).

   **Please note**: Patients enrolled in the manufacturer's patient support program (PSP) are eligible to receive free drug through the PSP until September 12, 2024, inclusive.

   After this date, patients who met the NDFP eligibility criteria at the point of treatment initiation are eligible to transition to NDFP funding for the remainder of their treatment course. Although sites may enroll their patient onto this policy at any time beforehand, any treatment claims submitted to eClaims that were given on or before the PSP transition date will be denied.

3. **My patient is currently receiving second-line systemic therapy for MF or SS. Are they eligible to switch to mogamulizumab?**

   If the patient's current treatment is effective and well tolerated, a switch to mogamulizumab is not required but could be considered if clinically appropriate. At point of disease progression, patients may be eligible for mogamulizumab as their next line of therapy provided all other eligibility criteria are met.

## Supporting Documents

None required at time of enrolment.

In the event of an audit or upon request, the following should be available to document eligibility:

- Histologically confirmed MF or SS of stage IB to IV.
- Clinic note(s) confirming prior treatment(s) and patient history/response.

Signature of Attending Physician (MRP-Most Responsible Physician): .....

..... ..... .....
Day Month Year

*Form 1050*