Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Gilteritinib (Inpatient) - Relapsed or Refractory FLT3-mutated Acute Myeloid Leukemia

(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

The patient must meet the following criteria:

Gilteritinib is used for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) whose FLT3 mutation status is confirmed by a validated test and who have a good performance status.

☐ Yes

3. Baseline Information

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

b. Is the patient transitioning from a private payer, compassionate program, or another funding program? ○ Yes ○ No

4. Funded Dose

Gilteritinib 120mg (three 40mg tablets) orally once daily in continuous 28-day cycles.

Treatment should continue as long as clinical benefit is observed or until unacceptable toxicity occurs.

In the absence of disease progression or unacceptable toxicity, treatment may be given for a minimum of six months to determine clinical benefit as a delay in clinical response can occur.

5. Notes

1. Funding is for doses administered in the inpatient setting only. Please refer to the Ministry of Health's Exceptional Access Program for funding of doses administered in the outpatient setting.
2. Gilteritinib funding is for single agent use only.
3. Patients who initiate treatment with gilteritinib in the relapsed or refractory AML setting who then proceed to a hematopoietic stem cell transplant (HSCT) would be able to resume gilteritinib following the HSCT. Claims should be submitted under the same form used for the initial course of treatment.
4. Gilteritinib is not funded if used for
    a. therapy-related AML;
    b. patients who have had a prior relapse while being treated with gilteritinib or another tyrosine kinase inhibitor (TKI) specific to FLT3-mutated AML in the relapsed or refractory AML setting;
    c. earlier lines of treatment prior to refractory or relapsed disease;
    d. AML with FLT3 mutations outside of FLT3-ITD, FLT3-TKD/D835, FLT3-TKD/I836.
5. After 1 cycle, dose escalations of up to 200mg once daily to achieve complete remission will be permitted but the dose should not be escalated after achieving complete remission.

6. FAQs

i. **My patient is currently receiving giltertinib through another funding source. Can my patient be transitioned over to receive funding through the High Cost Therapy Funding Program (HCTFP)?**

Provided the funding 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 gilteritinib under:

a. Ontario Health's HCTFP for doses administered in the inpatient setting. Please submit as a prior approval request including a copy of a validated test to confirm the FLT3 mutation status **at the time of relapse or determination of refractory disease** and a recent clinic note confirming the patient's response to therapy, if able to assess.
b. the Ministry of Health's Exceptional Access Program for doses administered in the outpatient setting. For further details, refer to the EAP website.

ii. **My patient was previously treated with midostaurin for FLT3-mutated AML. Is my patient eligible for gilteritinib?**

Patients who have received prior midostaurin or an alternative tyrosine kinase inhibitor would be eligible for gilteritinib, provided all other funding criteria are met.

iii. **My patient was able to proceed to a stem cell transplant following initial treatment with gilteritinib. Is my patient able to continue the gilteritinib?**

Gilteritinib will continue to be funded for patients who resume treatment following a hematopoietic stem cell transplant. For inpatient doses, claims should be submitted under the same form used for the initial course of treatment. For outpatient doses, please refer to the EAP website for more details.

iv. **My patient has already started treatment for relapsed/refractory FLT3-AML. Can I switch my patient to gilteritinib?**

The decision to switch should be based on a discussion between the clinician and patient. Provided all funding criteria are met, gilteritinib will be funded on a time-limited basis for patients who are currently receiving salvage chemotherapy for relapsed or refractory FLT3-AML (including patients who have not received a tyrosine kinase inhibitor as a component of previous salvage therapy in the relapsed or refractory setting and are in second or later hematologic relapse).

v. **How will treatment claims be managed in eClaims?**

Until planned updates are made to the HL7 interface, OPIS interface, and DSP submission specifications, claims for oral cancer drugs must be made manually through the eClaims web interface. **Claims must specify "inpatient" as the treatment setting.**

For this policy, eClaims expects to receive one 120 mg claim each day over the course of treatment although some patients may require dose escalation up to 200 mg once daily.

Supporting Documents

A validated test to confirm the FLT3 mutation status **at the time of relapse or determination of refractory disease** must be uploaded as part of the enrolment.

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

- A clinic note confirming the patient's treatment history and that treatment is being administered in the inpatient setting.

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

....
Day Month Year

Form 910