Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Midostaurin (Inpatient) - 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:

Midostaurin is used for the treatment of adult patients with newly diagnosed FMS-like tyrosine kinase 3 (FLT3)-mutated acute myeloid leukemia (AML). Patients should be deemed to be fit to receive standard induction and consolidation chemotherapy. ☐ Yes

3. Baseline Information

a. ECOG Performance Status at the time of enrolment ○ 0 ○ 1 ○ 2 ○ 3 ○ 4

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

c. If yes, how many **induction** doses has the patient received prior to transitioning to HCTFP funding? (1 dose = 50mg)

○ 1	○ 2	○ 3	○ 4	○ 5	○ 6	○ 7	○ 8	○ 9
○ 10	○ 11	○ 12	○ 13	○ 14	○ 15	○ 16	○ 17	○ 18
○ 19	○ 20	○ 21	○ 22	○ 23	○ 24	○ 25	○ 26	○ 27
○ 28	○ 29	○ 30	○ 31	○ 32	○ 33	○ 34	○ 35	○ 36
○ 37	○ 38	○ 39	○ 40	○ 41	○ 42	○ 43	○ 44	○ 45
○ 46	○ 47	○ 48	○ 49	○ 50	○ 51	○ 52	○ 53	○ 54
○ 55	○ 56							

d. If yes, how many **consolidation** doses has the patient received prior to transitioning to HCTFP funding (1 dose = 50mg)?

○ None	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6	○ 7	○ 8
○ 9	○ 10	○ 11	○ 12	○ 13	○ 14	○ 15	○ 16	○ 17
○ 18	○ 19	○ 20	○ 21	○ 22	○ 23	○ 24	○ 25	○ 26
○ 27	○ 28	○ 29	○ 30	○ 31	○ 32	○ 33	○ 34	○ 35
○ 36	○ 37	○ 38	○ 39	○ 40	○ 41	○ 42	○ 43	○ 44
○ 45	○ 46	○ 47	○ 48	○ 49	○ 50	○ 51	○ 52	○ 53
○ 54	○ 55	○ 56	○ 57	○ 58	○ 59	○ 60	○ 61	○ 62
○ 63	○ 64	○ 65	○ 66	○ 67	○ 68	○ 69	○ 70	○ 71
○ 72	○ 73	○ 74	○ 75	○ 76	○ 77	○ 78	○ 79	○ 80
○ 81	○ 82	○ 83	○ 84	○ 85	○ 86	○ 87	○ 88	○ 89
○ 90	○ 91	○ 92	○ 93	○ 94	○ 95	○ 96	○ 97	○ 98
○ 99	○ 100	○ 101	○ 102	○ 103	○ 104	○ 105	○ 106	○ 107
○ 108	○ 109	○ 110	○ 111	○ 112				

4. Funded Dose

Induction: Midostaurin 50mg orally twice daily on days 8 to 21 with each cycle, up to a maximum of 2 induction cycles, regardless of the funding source. Patients who have residual AML after a second induction cycle should be discontinued from midostaurin therapy.

Consolidation: Midostaurin 50mg orally twice daily on days 8 to 21 of each cycle of consolidation, up to a maximum of 4 cycles, regardless of the funding source.

5. Notes

1. Funding is for doses administered in the inpatient setting only. Please refer to the Ontario Drug Benefit Exceptional Access Program for funding of doses administered in the outpatient setting. Patients requiring outpatient treatment will need to apply to the Ontario Drug Benefit Program's Exceptional Access Program. At the initiation of therapy, please check that your patient will be eligible for benefits under the Ontario Drug Benefit Program. Some patients may require registration in the Trillium Drug Program.
2. Midostaurin is used in combination with standard induction chemotherapy with cytarabine and daunorubicin followed by standard cytarabine consolidation chemotherapy, OR any 7+3 induction regimen containing idarubicin followed by standard consolidation chemotherapy with cytarabine.
3. Midostaurin is not funded if used for
    a. maintenance therapy for AML;
    b. therapy-related AML after prior radiation therapy or chemotherapy for another cancer or disorder;
    c. re-induction and/or re-consolidation.

6. FAQs

i. **My patient is currently receiving midostaurin 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 midostaurin under:

a. Ontario Health's HCTFP for doses administered in the inpatient setting. Please submit as a prior approval request including a copy of the FLT3 test result and a recent clinic note confirming the patient's response to therapy, if able to assess.
b. The Ministry's Exceptional Access Program for doses administered in the outpatient setting. For further details, refer to the EAP website. Patients requiring outpatient treatment will need to apply to the Ontario Drug Benefit Program's Exceptional Access Program. At the initiation of therapy, please check that your patient will be eligible for benefits under the Ontario Drug Benefit Program. Some patients may require registration in the Trillium Drug Program.

Note that coverage is for a maximum of 2 induction cycles and 4 consolidation cycles, regardless of the funding source.

ii. **My patient had to be started on gemtuzumab ozogamicin while awaiting test results and now needs to be transitioned to midostaurin. Will my patient be eligible for coverage?**

Your patient may be eligible for midostaurin provided all other funding criteria are met. Sites are required to upload documentation of the validated test confirming the FLT3 mutation status.

iii. **My patient has started first-line treatment for AML prior to the public funding of midostaurin through HCTFP. Can I add midostaurin?**

On a time-limited basis, requests to add midostaurin will be considered provided all other funding criteria are met. Patients must currently be on standard induction and consolidation chemotherapy, and have not experienced disease progression or unacceptable intolerance during the first line treatment with the standard chemotherapies being used. Please submit as a prior approval request including a copy of the FLT3 test result and a recent clinic note confirming the patient's response to therapy, if able to assess.

iv. **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 two 50mg doses each day over the course of treatment. Claims for higher doses representing multiple days of treatment will be auto-denied by eClaims.

Supporting Documents

A validated test to confirm the FLT3 mutation status of AML 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 administered in the inpatient setting.

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

Day Month Year

Form 908