Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

# Arsenic Trioxide - Relapsed/Refractory Induction of Acute Promyelocytic Leukemia (APL)

(This form must 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 (comple 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

a. The patient must meet the following criteria:

- Arsenic trioxide will be used in combination with all-trans retinoic acid (ATRA) in the relapsed/refractory setting for acute promyelocytic leukemia (APL) as an induction treatment. ☐ Yes

## 3. Funded Dose

Please select one of the following regimens:

○ Low to Intermediate Risk (WBC $\leq$ 10 x $10^9$/L)
(APL0406) - Arsenic trioxide is administered intravenously at a dose of 0.15mg/kg/day until complete remission.

○ High Risk (WBC > 10 x $10^9$/L)
(APML4) - Arsenic trioxide is administered intravenously at a dose of 0.15mg/kg daily on days 9 to 36.

## 4. Treatment History

a. Has the patient previously received arsenic trioxide **not** funded through NDFP? ○ Yes ○ No

- If yes, what dosage was prescribed? .....

## 5. Notes

1. A separate enrolment is required for consolidation treatment with arsenic trioxide.

2. Arsenic must be administered with ATRA. The ATRA portion is not funded by Ontario Health (Cancer Care Ontario) and therefore, it is advised that sites confirm ATRA will be covered by another funding source prior to initiation of therapy.

## 6. 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:

- A copy of the bone marrow report and a validated genetic analysis (e.g. cytogenetics, FISH, PCR) to confirm diagnosis of APL with t(15:17) translocation and PML/RAR-alpha gene expression.

- If both the t(15:17) translocation and PML/RAR-alpha gene expression are not confirmed, please also include the results of the confirmatory diagnostic test that was performed.

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

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