Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Arsenic Trioxide - Relapsed/Refractory Consolidation 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 a consolidation 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, in combination with ATRA, is administered intravenously at a dose of 0.15mg/kg/day for 5 days per week, 4 weeks on and 4 weeks off, for a total of 4 cycles.
APL0406 consolidation is NOT followed by maintenance.

○ High Risk (WBC > 10 x 10^9/L)
(APML4) - Two cycles of arsenic trioxide are administered as follows:
Cycle 1: Arsenic trioxide 0.15 mg/kg/day days 1-28
Cycle 2: Arsenic trioxide 0.15mg/kg/day IV on Days 1 to 5, 8 to 12, 15 to 19, 22 to 26, 29 to 33
APML4 consolidation IS followed by maintenance.

○ High Risk (WBC > 10 x 10^9/L)
(APL0406) – Arsenic trioxide, in combination with ATRA, is administered intravenously at a dose of 0.15mg/kg/day for 5 days per week, 4 weeks on and 4 weeks off, for a total of 4 cycles.
APL0406 consolidation is NOT followed by maintenance.

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. 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

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