

Treosulfan (Outpatient) - Conditioning Pre-Stem Cell Transplant for Acute Myeloid Leukemia or Myelodysplastic 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 (m²): * 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)

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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:

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b. Intended regimen schedule:

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c. Intended regimen:

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d. Drug(s) to be held:

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e. Rationale for holding drug(s):

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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):

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h. Anticipated date of first treatment:

.....
Day Month Year

i. Additional comments:

2. Eligibility Criteria

Treosulfan will be used (in combination with fludarabine) as part of a pre-allogeneic hematopoietic stem cell transplant (alloHSCT) conditioning regimen for adult patients with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS) who are at *increased risk from standard conditioning therapies.

☐ Yes

*Patients must:

- Be 50 years of age or older at transplant and/or have a hematopoietic cell transplantation-specific comorbidity index (HCT-CI) score greater than 2, with a good performance status

Patients must not have:

- Active central nervous system involvement and/or
- Received an alloHSCT.

3. Baseline Information

- a. Does this patient have an enrolment for the inpatient version of this policy? ☐ Yes ☐ No
- a. ECOG Performance Status at the time of enrolment ☐ 0 ☐ 1 ☐ 2
- c. Diagnosis ☐ Acute Myeloid Leukemia ☐ Myelodysplastic Syndrome

4. Funded Dose

Treosulfan 10,000 mg/m² intravenously (IV) on three consecutive days (days -4, -3 and -2) before stem cell infusion (day 0).

5. Notes

1. Enrolment in this policy is for funding of treosulfan doses administered in the outpatient setting only. For the funding of doses administered in the inpatient setting, a separate enrolment form must be submitted. See the policy Treosulfan (Inpatient) - Conditioning Pre-Stem Cell Transplant for Acute Myeloid Leukemia or Myelodysplastic Syndrome

Please ensure all claims are submitted through eClaims under the appropriate policies for inpatient and outpatient administered doses.

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:

- Clinic note(s) outlining patient's diagnosis, treatment history, and type of conditioning regimen used.
- Clinic note specifying the hematopoietic cell transplantation-specific comorbidity index (HCT-CI) score, or alternate clinical documentation outlining the increased risk from standard conditioning therapies.

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

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Day Month Year