

ALL Response Criteria

Primary Induction Failure (PIF)

The patient received treatment for ALL but **never achieved complete remission at any time**. PIF is not limited by the number of unsuccessful treatments; this disease status only applies to recipients who have *never been in complete remission*.

Complete Remission (CR)

Hematologic complete remission is defined as meeting **all** of the following response criteria for at least four weeks.

- < 5% blasts in the bone marrow
- Normal maturation of all cellular components in the bone marrow
- No extramedullary disease (e.g., CNS, soft tissue disease)
- ANC (absolute neutrophil count) $\geq 1,000/\mu\text{L}$
- Platelets $\geq 100,000/\mu\text{L}$
- Transfusion independent

Alternative post-transplant CR criteria are accepted in the setting of pediatric ALL when the center does not routinely perform bone marrow biopsies post-transplant and the patient was in CR pre-transplant. These criteria are not used for pre-transplant ALL disease status. The criteria are as follows:

- Complete donor chimerism ($\geq 95\%$ donor chimerism without recipient cells detected)
- No extramedullary disease (e.g., CNS, soft tissue disease)
- Neutrophils $\geq 1,000/\mu\text{L}$
- Platelets $\geq 100,000/\mu\text{L}$
- Transfusion independent

In some cases, there may not be a four-week interval between completion of therapy and the pre-transplant disease assessment; in this case, CR should still be reported as the status at transplant, since it represents the “best assessment” prior to HCT. This is an exception to the criteria that CR be durable beyond four weeks. The pre-transplant disease status should not be changed based on early relapse or disease assessment post-transplant.

Include recipients with persistent cytogenetic or molecular abnormalities who meet the above CR criteria for hematologic CR.

Include recipients meeting the above CR criteria regardless of how many courses of therapy were required to achieve CR.

The number of this complete remission can be determined by using the following guidelines:

- 1st CR: no prior relapse
- 2nd CR: one prior relapse
- 3rd or higher: two or more prior relapses

Relapse (REL)

Relapse is defined as the recurrence of disease after CR, meeting at least one of the following criteria:

- $\geq 5\%$ blasts in the marrow or peripheral blood
- Extramedullary disease
- Disease presence determined by a physician upon clinical assessment

The number of this relapse can be determined by using the following guidelines:

- 1st relapse: one prior CR
- 2nd relapse: two prior CRs
- 3rd or higher: three or more CRs

Do not include a partial response (PR) when determining number of relapse. Recipients who achieve a PR to treatment should be classified as either PIF or relapse; PR in ALL is generally of short duration and is unlikely to predict clinical benefit.

No Treatment

The recipient was diagnosed with acute leukemia and never received therapeutic agents. Include patients who have received only supportive therapy, including growth factors and/or blood transfusions.

Date	Manual Section	Add/Remove/Modify	Description
------	----------------	-------------------	-------------

8/ 26/ 16	ALL Response Criteria	Add	Added alternative post-HCT CR criteria for pediatric recipients.
8/ 26/ 16	ALL Response Criteria	Modify	Updated relapse criteria: Relapse is defined as the recurrence of disease after CR, meeting <i>at least one of</i> the following criteria