Response assessment in patients with CLL

Treatment response assessment monitoring guidance and checklist

Includes best practice sharing by
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Timing of response assessment:[1,2]

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- Assessment of response should include a careful physical examination and evaluation of the blood and BM
- The timing of response assessment for therapies with a defined treatment duration, such as CIT approaches, should be at least **2 months** after completion of therapy
- To define the response to therapy, two groups of parameters need to be assessed and documented: parameters of **group A** assess the lymphoid tumour load and constitutional symptoms; parameters of **group B** assess the haematopoietic system (see **overview of response assessment** for further details)
- For continued therapies or treatment strategies that contain a maintenance phase, the assessment of response should be performed at least **2 months** after patients achieve their maximum response,* or a time point predefined in the protocol. It is not necessary to interrupt therapy for response assessment
- Where appropriate, a further assessment of response (ie, BM assessment) may be performed at least **2 months** after the patient has cleared MRD† from the peripheral blood in clinical trials

Timing of response assessment in practice:[3]

3–4 months

6–12 months

- Monitoring and testing will vary depending on the dynamic nature of disease
- Monitoring will always need to be tailored for the individual patient depending on:
  - ✓ Patient's symptoms
  - ✓ The treatment prescribed
  - ✓ Response to treatment
  - ✓ Blood results
  - ✓ Speed to achieve remission
  - ✓ Side effects of the medications

Expert HCP insight Dr Ali Rismani

- Response assessment does not need to be done at every appointment
- It is important to make sure enough time is given for a treatment to show effectiveness
- It is also important to do response assessment **at appropriate intervals** to make sure the treatment is **effective** and there is no need to change management
- The first assessment should be done at **3–4 months** and again at **6 months** and **12 months**

Based on the information outlined in this guidance, the below checklist can be used to aid patient monitoring through the treatment pathway.

Signs/symptoms

❑ Fevers	❑ Enlarged liver	Cumulative illness rating scale ❑ ≤6 ❑ >6
❑ Night sweats	❑ Fatigue	❑ Adequate function status
❑ Weight loss	❑ Shortness of breath	ECOG performance status ❑ 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4
❑ Enlarged lymph nodes	❑ Enlarged spleen	Patient fitness ❑ Frail, significant comorbidities
	❑ Other:	

Tests

Baseline tests are not repeated at follow-up unless patient is progressing or starting treatment.

Routine follow-up tests

- ❑ Full blood count
- ❑ Physical examination
- ❑ Renal/liver function test
- ❑ Protein electrophoresis

Routine follow-up considerations

- ❑ Any changes in the clinical picture as flagged following routine follow-up tests can lead to further investigations and repeating of relevant tests performed at baseline
- ❑ Staging: Not repeated unless there has been a change
- ❑ *IGHV*/CD38 or FISH: Repeated if patient is starting treatment in order to evaluate evolution of disease

Treatment status

❑ Active monitoring	❑ Treatment complete, CR	❑ Refractory disease
❑ Active treatment	❑ Treatment complete, PR	❑ Relapsed

Response to treatment

Response to therapy:

- ❑ Complete
- ❑ Complete response, unconfirmed
- ❑ Partial
- ❑ Stable disease
- ❑ Relapse disease
- ❑ Progressive disease

Reason for stopping treatment:

- ❑ Completed
- ❑ Progression of disease on treatment
- ❑ Toxicity of treatment
- ❑ Comorbid illness
- ❑ Other

BM, bone marrow; CD, cluster of differentiation; CIT, chemoimmunotherapy; CLL, chronic lymphocytic leukaemia; CR, complete response; ECOG, Eastern Cooperative Oncology Group; FISH, fluorescence in situ hybridisation; Hb, haemoglobin; *IGHV*, immunoglobulin heavy chain variable; LDH, lactate dehydrogenase; MRD, minimal residual disease; NP, not performed; PR, partial response
*Maximum response can be defined as a treatment phase in which no additional improvement is seen during at least 2 months of therapy; †Refer to Response assessment in CLL document for further information

1. Hallek M, Al-Sawaf O. Am J Hematol 2021;96:1679–1705; 2. Hallek M, et al. Blood 2018;131:2745–60; 3. RM Partners West London Cancer Alliance. Pan-London Haemato-Oncology Clinical Guidelines. Available at: https://rmpartners.nhs.uk/wp-content/uploads/2020/01/Pan-London-CLL-Guidelines-Jan-2020.pdf. Accessed 9 January 2023

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