

Transcript Details

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Optimizing Monitoring after Ide-cel in RRMM: What the Evidence Shows

Announcer:

You're listening to *AudioAbstracts* on ReachMD, and this episode is brought to you by Bristol Myers Squibb. Here's Dr. MiMi Maeusli.

Dr. Maeusli:

Hi, I'm Dr. Mimi Maeusli. Today, I'll be discussing new findings on post-infusion monitoring for idecabtagene vicleucel, or ide-cel, which were presented at the 22nd International Myeloma Society Annual Meeting in September 2025.

CAR T-cell therapy has significantly changed the outlook for people with relapsed or refractory multiple myeloma, but it carries known risks, including cytokine release syndrome, or CRS, and neurotoxicity, such as ICANS. As more patients become eligible for these therapies, we need to understand how long we should monitor for these events after infusion without adding strain on the healthcare system.

A new study on ide-cel, a BCMA-directed CAR T-cell therapy, examined CRS and neurotoxicity events in about 350 patients from clinical trials—the KarMMa and KarMMa-3 studies—along with real-world data from almost 1000 patients in the CIBMTR registry who received ide-cel.

So, what did they find? Well, CRS events showed a clear and consistent pattern, occurring in almost 90 percent of trial participants and just under 85 percent of patients in real-world settings. Across all cohorts, most CRS events were low-grade, and over 95 percent of first events occurred in the first week after infusion. In fact, the median onset was one to two days, with events typically resolving within three to four days.

Now, neurotoxicity events followed a similar pattern across study settings. In the trials, about 40 percent of participants experienced investigator-identified neurotoxicity, and in the real-world data, about 30 percent experienced ICANS. Again, most events were low grade, with over 80 percent of first neurotoxicity events occurring during the first week after infusion. Similar to CRS, most of these events resolved within three to four days.

And when both CRS and neurotoxicity were considered together, these trends held across study cohorts with over 80 percent of all first events reported during the first week.

These results align with recent FDA updates to the Risk Evaluation and Mitigation Strategy, or REMS, for ide-cel, which requires seven days of post-infusion monitoring. The REMS update also shortens the time that patients are required to remain near a certified treatment center, from four weeks to two weeks post-infusion.

But let's keep in mind that clinical trials may identify mild symptoms more consistently than real-world practice because they use structured assessments. And registry data may not have complete event information, such as date of onset or severity. Observational data also can't rule out the effect of other factors on these events, such as having exposure to other multiple myeloma therapies.

Even with these factors in mind, for clinicians who treat individuals with ide-cel, the takeaway is clear: the first week after infusion is the key window to monitor for CRS and neurotoxicity. The updated REMS reflects this timing and reduces the monitoring burden for patients and treatment centers. By shortening the required stay near a certified facility, these changes may broaden access for people who couldn't manage extended travel or lodging.

So this may help more individuals with relapsed or refractory multiple myeloma receive a therapy that can offer meaningful benefit when few options remain—and that's an important step forward.

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Reference

Sidana S, Raje N, Hansen D, et al. Optimizing post-chimeric antigen receptor (CAR) T-cell monitoring: evidence across idecabtagene vicleucel (ide-cel) pivotal clinical trials and real-world experience. Poster PA-078 presented at the 22nd International Myeloma Society Annual Meeting; September 17–20, 2025; Toronto, Canada.