

# Optimizing post-treatment monitoring following CAR T-cell therapy: Policy changes and adverse event data



Due to the risk of CRS and neurological toxicities, approved CAR T-cell therapies were previously only available under the REMS safety program.<sup>1,2</sup>



On June 27, 2025, the FDA removed the REMS requirements for all approved BCMA- and CD19-directed autologous CAR T-cell therapies, based on consistent safety data from clinical trials and real-world studies.<sup>1,2</sup>

## Key requirements for autologous CAR T-cell therapies before and after the FDA removal of REMS<sup>3</sup>

|   | Before  | After                               |
|---|---|-------------------------------------|
| Institutional certification                               | Required at REMS-approved sites                             | Not required                        |
| Tocilizumab availability                                  | On-site and immediately accessible                          | Not required                        |
| Prescriber / staff training                               | REMS-specific certification                                 | Integrated into product labelling   |
| Patient proximity to a healthcare facility after infusion | 4 weeks within a 2-hour radius (often stricter in practice) | 2 weeks within reasonable proximity |
| Driving restriction                                       | 8 weeks   | 2 weeks                             |

## Optimizing post-CAR T-cell monitoring<sup>4</sup>

An analysis by Kamdar *et al.* assessed the timing of CRS and ICANS in patients treated with liso-cel in clinical trials or real-world SoC settings using the CIBMTR registry.

**Population:**  
N = 1,579

**Clinical trial data (n = 702)**

**CIBMTR registry data\* (n = 877)**

Pooled data from 5 trials of liso-cel in patients with R/R LBCL, CLL/SLL, FL, and MCL (TRANSCEND NHL-001, TRANSCEND CLL-004, TRANSFORM, PILOT, TRANSCEND FL)

Patients with R/R LBCL who received liso-cel and had  $\geq 1$  reported assessment after infusion

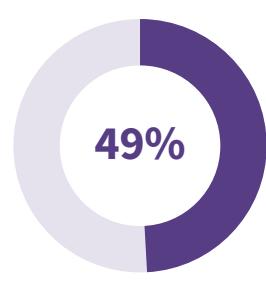
\*Data were collected between February 2021 and May 2024.

## CRS and ICANS

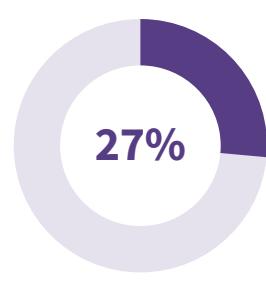
CRS and NEs



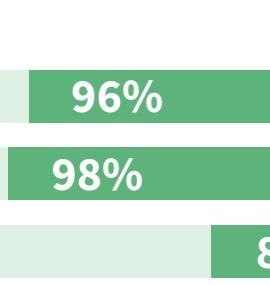
CRS



NEs



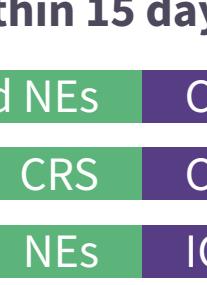
CRS and ICANS



CRS



ICANS



### Median time to onset

CRS 5 days

NEs 8 days

CRS 4 days

ICANS 6 days

### Maximum Grade $\geq 3$

CRS 3%      CRS 3%

NEs 10%      ICANS 10%

## Onset within 15 days of infusion

96%

CRS and NEs

96%

98%

CRS

97%

88%

NEs

95%

The analysis demonstrates that most CRS/NEs/ICANS events occurred within 15 days of liso-cel infusion and most were not severe. These data support new policy requirements introduced following the FDA removal of REMS (patients to remain within a reasonable proximity to a healthcare facility and not drive for 2 weeks).<sup>3,4</sup> The removal of the REMS requirement for approved autologous CAR T-cell therapies, and data to inform optimal monitoring requirements, may help expand access to these therapies while maintaining patient safety.<sup>3</sup>

**Abbreviations:** BCMA, B-cell maturation antigen; CAR, chimeric antigen receptor; CIBMTR, Center for International Blood and Marrow Transplant Research; CLL, chronic lymphocytic leukemia; CRS, cytokine release syndrome; FDA, U.S. Food and Drug Administration; FL, follicular lymphoma; ICANS, immune effector cell-associated neurotoxicity syndrome; LBCL, large B-cell lymphoma; liso-cel, lisocabtagene maraleucel; MCL, mantle cell lymphoma; NE, neurological event; REMS, Risk Evaluation and Mitigation Strategies; R/R, relapsed/refractory; SLL, small lymphocytic lymphoma; SoC, standard of care.

**References:** 1. FDA. <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-eliminates-risk-evaluation-and-mitigation-strategies-rems-autologous-chimeric-antigen-receptor>. Published Jun 26, 2025. Accessed Dec 1, 2025; 2. FDA.

<https://www.fda.gov/news-events/press-announcements/fda-eliminates-risk-evaluation-and-mitigation-strategies-rems-autologous-chimeric-antigen-receptor>. Published Jun 27, 2025. Accessed Dec 1, 2025; 3. Orosco-Tamina AL, *et al*. *Cancer (Basel)*. 2025;17(19):3216; 4. Kamdar M. Poster Abstract #7026. 2025 ASCO Annual Meeting; May 30 – Jun 3, 2025; Chicago, US.



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