Neurological Adverse Events Across FDA-Approved CAR T-Cell Therapies: A FAERS Pharmacovigilance Analysis

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Background

- CD19-targeted CAR T-cell therapy improves survival in B-cell lymphoma; BCMA-targeted CAR T-cell therapy improves survival in relapsed/refractory multiple myeloma.
- All six FDA-approved products carry a well-documented neurotoxic side-effect profile that remains incompletely characterized.
- Aim: describe the demographics of the most common neurologic adverse events to support earlier diagnosis and improved quality of life.

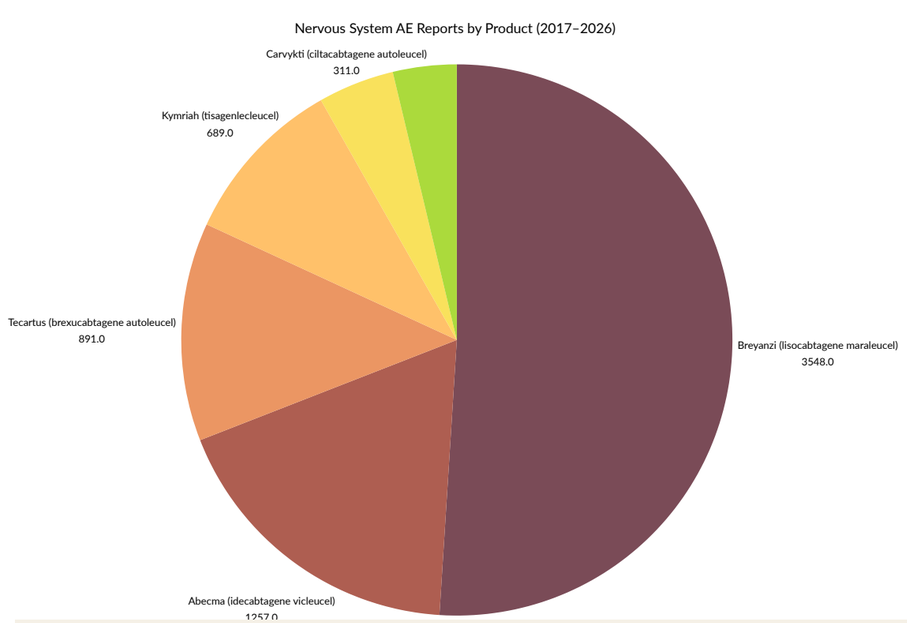
CAR T-Cell Products Studied

Yescarta *axicabtagene ciloleucel* — CD19	**Kymriah** *tisagenlecleucel* — CD19
Breyanzi *lisocabtagene maraleucel* — CD19	**Tecartus** *brexucabtagene autoleucel* — CD19
Abecma *idecabtagene vicleucel* — BCMA	**Carvykti** *ciltacabtagene autoleucel* — BCMA

Methods

- Retrospective pharmacovigilance study using the FDA Adverse Event Reporting System (FAERS) Public Dashboard, 2017–present.
- Each of the 6 CAR T-cell therapies searched individually within the "Drugs and Biologics" section.
- Nervous system disorder cases, ICANS, neurotoxicity, and other neurologic reactions extracted from "Cases by Reaction."
- Frequencies and percentages calculated relative to total reported adverse events for each therapy.

Results



17%	**Neurotoxicity** 3,012 cases
16.8%	**ICANS** 2,914 cases
2%	**Headache** 414 cases
2%	**Tremor** 354 cases
1.5%	**Parkinsonism (Carvykti signal)** 268 cases

Toxicity signatures diverge by product: Yescarta shows the highest overall volume of acute neurotoxicity, while Carvykti shows a distinctive, disproportionate parkinsonism signal — evidence that no single monitoring protocol fits all six CAR T-cell products.

From 2017–2026, 6,956 nervous system adverse events were reported across all six CAR T-cell products. **ICANS and neurotoxicity were the most common, together accounting for nearly 34% of all events.**

Clinical Implications

Earlier Diagnosis
Recognize neurologic signals sooner after CAR T-cell infusion.

Product-Specific Monitoring
Tailor surveillance to each product's distinct toxicity signature.

Improved Quality of Life
Reduce morbidity from unrecognized or delayed-treated neurotoxicity.

Proposed Product-Specific Monitoring Framework

Risk Level	CAR-T	Recommended Surveillance
High Acute Risk	Axicabtagene (Yescarta)	Daily ICANS scoring Days 1-14 + early neurology consult
Intermediate Risk	Tisagenlecleucel, Brexucabtagene	Standard ICANS grading + headache/tremor diary
Delayed Movement Disorder Risk	Ciltacabtagene	Extended follow-up 12 months for parkinsonism
Lower Volume but Persistent Risk	Lisocabtagene, Idecabtagene	Routine neuro checks + patient education

Monitoring aligned to product-specific safety profile • For clinical reference only

Conclusion

- This FAERS analysis confirms a significant, heterogeneous neurological burden across all six FDA-approved CAR T-cell therapies.
- Divergent toxicity signatures — high-volume neurotoxicity with Yescarta vs. the distinctive parkinsonism signal with Carvykti — argue against a one-size-fits-all approach.
- Product-specific, prospective neurological surveillance could enable earlier diagnosis and meaningfully improve quality of life.

Acknowledgements

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References

- U.S. Food & Drug Administration. FDA Adverse Event Reporting System (FAERS) Public Dashboard. Accessed 2026.
- U.S. prescribing information for Yescarta, Kymriah, Breyanzi, Tecartus, Abecma, and Carvykti.