

International Consensus Sets Updated Framework for CAR T-Cell Therapy in Severe Autoimmune Diseases

EBMT, ISCT and JACIE experts, with EULAR and ECTRIMS representatives, call for careful patient selection, multidisciplinary care and long-term follow-up as CAR T-cell therapy expands beyond cancer.

An international multidisciplinary group of 31 experts has updated consensus recommendations to guide the use of CAR T-cell therapy in patients with severe, treatment-refractory autoimmune diseases. Published in *The Lancet Rheumatology*, these 2026 recommendations were developed jointly by EBMT, ISCT and JACIE, with contributions from representatives of EULAR and ECTRIMS. They update the first best-practice recommendations released in 2024.

The update reflects the rapid expansion of CAR T-cell therapy beyond cancer and growing clinical experience across autoimmune diseases. The recommendations cover rheumatological, neurological, haematological and paediatric indications and provide guidance on patient selection, diagnostic assessment, treatment planning, clinical management, follow-up and immune monitoring.

While early clinical experience has shown promising results in some patients whose disease has not responded to existing therapies, the expert panel stresses that CAR T-cell therapy remains an evolving field. The recommendations were therefore developed using EBMT's structured practice harmonisation methodology, designed for areas where high-level evidence is still emerging.

A Common Framework for Patient Selection and Care

The consensus recommends considering CAR T-cell therapy for patients with severe autoimmune diseases that remain active or progressive despite appropriate standard treatment. Whenever possible, treatment should be delivered within clinical trials. When trials are unavailable, decisions should be made through a documented multidisciplinary assessment involving both autoimmune disease specialists and haematology or cellular therapy experts.

The experts also recommend treatment in experienced centres, preferably FACT/JACIE-accredited for immune effector cell therapies, to ensure consistent quality and safety standards. Because autoimmune diseases vary widely in organ involvement, comorbidities and previous treatments, disease-specific assessment and monitoring remain essential.



“CAR T-cell therapy is emerging as an important new therapeutic approach for patients with severe and refractory autoimmune diseases. However, this remains a rapidly evolving field, and careful patient selection, multidisciplinary management and long-term follow-up are essential. These recommendations provide a shared framework to support patient safety and greater consistency in clinical practice while we continue to build the evidence base.” said **Raffaella Greco** (Milano, San Raffaele Hospital) and **Dominique Farge** (Paris, St-Louis Hospital), coordinators of the consensus recommendations.

Building the Long-Term Evidence Base

The recommendations place strong emphasis on activities before and after CAR T-cell infusion, including diagnostic assessment, treatment planning, immune monitoring and management of treatment-related toxicities. They also highlight the importance of distinguishing inflammatory complications related to CAR T-cell therapy from progression or flare of the underlying autoimmune disease, requiring close collaboration between haematology, cellular therapy and autoimmune disease specialists teams.

Long-term follow-up and systematic data collection are key priorities. The panel strongly recommends reporting patients treated with CAR T-cell therapies to the EBMT Registry to improve understanding of long-term outcomes, durability of response and late toxicities, as recently emphasised by the FDA and the EMA. The registry has been expanded to support follow-up of patients with autoimmune diseases across participating centres.

Specific guidance is also provided for children and adolescents, where evidence remains limited. Recommendations emphasise multidisciplinary assessment that considers disease severity, previous treatments, organ damage, development, fertility, quality of life and the long-term effects of chronic immunosuppression.

An International Multidisciplinary Consensus

The recommendations were developed through a structured international consensus process involving experts in haematopoietic cell transplantation, CAR T-cell therapy and autoimmune diseases from multiple specialties and countries. The authors highlight priorities for future research, including larger controlled clinical trials, biomarkers of response and toxicity, novel CAR targets and strategies to improve treatment access. They emphasise that long-term follow-up registry data will be critical in defining the role of CAR T-cell therapy across different autoimmune diseases.

The 2026 recommendations are intended as living guidance under the auspices of EBMT, ISCT and JACIE and will continue to evolve as new evidence and clinical experience emerge.

Access the publication: [https://www.thelancet.com/journals/lanrhe/article/PIIS2665-9913\(26\)00249-3/abstract](https://www.thelancet.com/journals/lanrhe/article/PIIS2665-9913(26)00249-3/abstract)

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Through collaboration, research, education and quality improvement, we support the advancement of haematopoietic cell transplantation, cellular and gene therapies while connecting healthcare professionals, researchers and institutions around the world.

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