



PRESS RELEASE

German health insurance regulator directs centres to report commercial CAR-T treatments to the EBMT Registry

Barcelona, Tuesday 17, November, 2020 – On 17 September 2020, the Gemeinsame Bundesausschuss (G-BA) published its directions on the treatment of German patients with CAR T-cell therapies (https://www.g-ba.de/downloads/39-261-4477/2020-09-17_AM-RL_CarT-Zellen-QS-Ma%C3%9Fnahmen.pdf). According to the decision, beside structural and qualification requirements, the treating facilities must report patients to the German Register for Stem Cell Transplantation (DRST), the Pediatric Register for Stem Cell Transplantation (PRST) or the European Society for Blood and Marrow Transplantation (EBMT) Registry. Reporting data is a condition for reimbursement of CAR T cell costs to hospitals treating patients with these new therapies.

The Gemeinsame Bundesausschuss (G-BA) or Federal Joint Committee in English is the highest decision-making body of the joint self-government of physicians, dentists, hospitals and health insurance funds in Germany. It issues directives for the benefit catalogue of the statutory health insurance funds (GKV) for more than 73 million insured persons and thus specifies which services in medical care are reimbursed by the GKV. The G-BA is subject to the statutory supervision of the Federal Ministry of Health (<https://www.g-ba.de/english/>)

The EBMT welcomes the G-BA decision as an important step forward towards centrally registering all European patients treated with CAR T-cell therapies. EBMT encourages other authorities to engage with the principal European cell therapy registry, as qualified by the European Medicines Agency (https://www.ema.europa.eu/en/documents/scientific-guideline/qualification-opinion-cellular-therapy-module-european-society-blood-marrow-transplantation-ebmt_en.pdf), offering a single source of comprehensive data to support benefit-risk monitoring of these products, regulatory decision making and collaborative studies. EBMT is engaged in continuous dialogue with all stakeholders that contribute to ongoing developments in the cellular therapy field through the GoCART initiative.

About the European Society of Blood and Marrow Transplantation (EBMT)

The EBMT is a not-for-profit medical and scientific organisation established in 1974. It is dedicated to fighting life-threatening blood cancers and diseases and improving patients' lives with more than 5,000 physicians, nurses, scientists and other healthcare professionals - participating in a unique collaborative network of peers involved in haematopoietic stem cell transplantation (HSCT) and cellular therapy research.

The Registry is the backbone of the EBMT. It is the only data source of its kind in Europe. The data is submitted continuously by EBMT centre members. The Registry has data on HSCT procedures including details on disease, transplant type, donor type and stem cell source. It contains data on patients that have undergone HSCT and also patients receiving immunosuppressive therapies or cellular therapies. The Registry also offers the possibility to enter donors' follow-up data, which is crucial to ensure maximum donor safety.

The Registry underpins extensive European research that translates into changes in clinical practice and improvements in patient outcome and care.

- For further information about the EBMT, please visit www.ebmt.org
- Follow EBMT on LinkedIn ([EBMT](#)), Twitter ([@TheEBMT](#)) and Facebook ([TheEBMT](#))



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About the GoCART Coalition

GoCART is a multi-stakeholder coalition in the field of gene and cellular therapies manufactured from cells and tissues of hematopoietic origin. This new Coalition brings together stakeholders from across the sector, including patients, health care professionals, health authorities, HTA bodies and reimbursement agencies, pharmaceutical companies and medical non-profit organisations.

The aim of GoCART is to promote patient access to novel cellular therapies and to contribute health and well-being through innovation by multi-stakeholder collaboration on clinical data, standards of care, centre qualification, education and policy.

- For further information about GoCART, please visit www.ebmt.org/ebmt/gocart-coalition
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