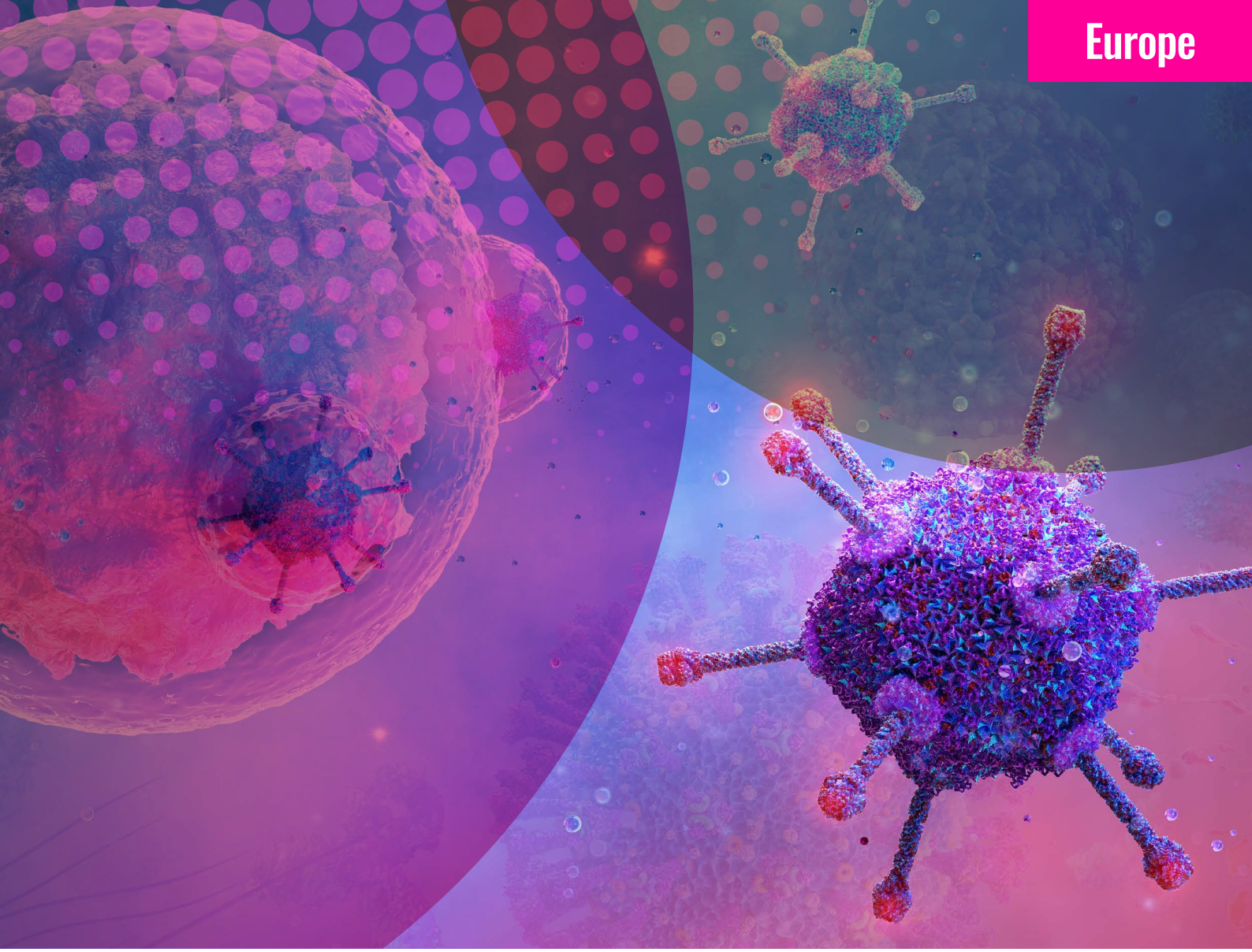


Europe

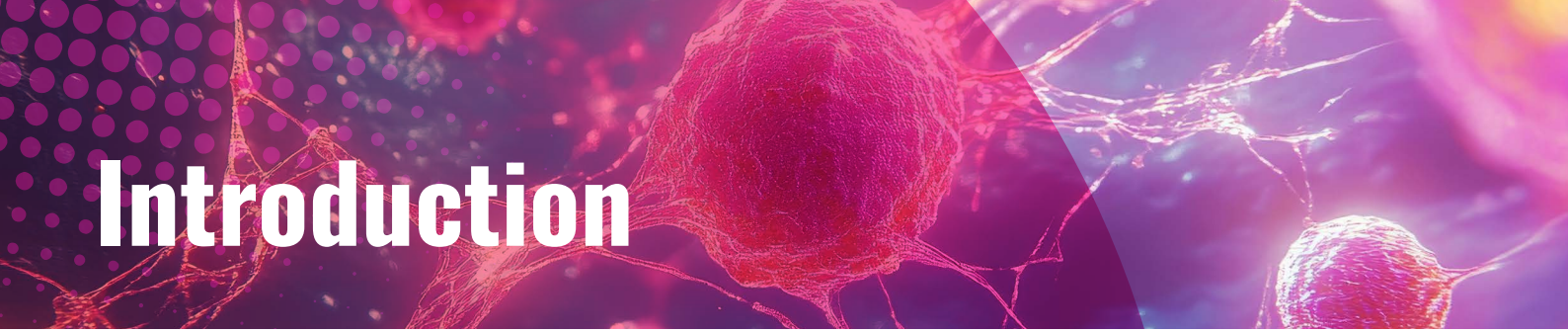
CAR T VISION

Vision to Action Blueprint

Actions to improve access to CAR T-cell therapy in Europe

October 2026

CAR T Vision activities and outputs are led by an independent Steering Committee, made possible through funding from industry supporters Gilead and Kite, Autolus and J&J.



Introduction

Although CAR T-cell therapy has been available in Europe since 2018, offering the potential for cure in certain advanced blood cancers, only approximately two in 10 eligible patients receive access to it.[1*]

Patients continue to face multiple, interlinked barriers along the care pathway, including delayed or missed referral, limited treatment capacity concentrated in a small number of specialist centers, inefficient referral and coordination processes, prolonged times from referral to treatment, and persistent funding and reimbursement challenges that can delay or restrict access after regulatory approval.[1,2,3] These barriers mean that access varies substantially by geography and socioeconomic circumstance, and too many patients deteriorate or lose eligibility before receiving therapy.[4]

These challenges were outlined in the CAR T Vision inaugural report launched in June 2025. The report set out a **Vision to double the proportion of eligible patients treated with CAR T-cell therapy by 2030**, alongside a set of imperatives for the desired future state of CAR T-cell therapy access. To translate these into implementable steps, the CAR T Vision Steering Committee – in consultation with a wider group of experts – developed a Blueprint comprised of priority actions and indicators to help ensure patients can receive this life-changing therapy when they need it most.

From Vision to Action: A Blueprint

Recommended actions

This Blueprint outlines a **clear set of actionable interventions**, which policymakers, payors, patient advocacy organizations, healthcare providers, and manufacturers in the European ecosystem (i.e., EU/EEA member states, the UK, and Switzerland) can adopt to **enhance the knowledge, capacity, resources, and financial viability** to sustain and expand the delivery of CAR T-cell therapy – especially as its use broadens to new indications. It also includes **real-world examples and case studies** of where these actions are already being taken forward as inspiration.

Indicators

To track progress over time, the Blueprint also recommends **one indicator per Vision goal**, advancing our collective understanding of whether policies or systems in place are working for patients. These indicators have been selected to be meaningful, feasible to measure, and suitable for consistent reporting on an annual basis, enabling stakeholders to assess improvement in practice and to identify where further action is required. The Vision will establish a baseline against these indicators in 2026 and begin measuring progress annually from 2027, initially focusing on the UK, Spain, Italy, Germany, and France, where there is the longest history of CAR T-cell therapy use. Other countries are encouraged to adopt the Blueprint and contribute data and case studies to the Vision, supporting knowledge sharing and learnings.

* Estimate based on an analysis of the share of relapsed or refractory large B-cell lymphoma patients treated with at least two lines of therapy (LBCL 2L+ R/R population) in Italy, France, Germany, Spain and the United Kingdom.

A Call to Action

We invite stakeholders to use this Blueprint as a framework to strengthen existing policies and drive practical solutions that ensure more eligible patients can access CAR T-cell therapy and benefit from its curative potential, drawing from the examples provided. The CAR T Vision will continue to collate case studies of initiatives that are driving progress toward the Vision goals and align with the actions we have highlighted.

If you are working on programs you would like the Vision to spotlight, please contact visionforcart@incisivehealth.com.



Vision Goal 1: Increase awareness and understanding of CAR T-cell therapy

Indicator

Proportion of patients, care partners, referring clinicians, and multidisciplinary teams (MDTs) who feel well informed about CAR T-cell therapy and the referral process.

Recommended actions

- Referring centers, treating centers, professional societies, and medical education providers collaborate on structured guidance, mentorship, and training programs to facilitate clinician understanding of patient eligibility, early patient identification, and referral processes.
- Referring clinicians and treating clinicians provide patients and care partners with clear, accessible, and tailored resources early in the care pathway to support informed decision-making and address any concerns (e.g., decision aids, peer-to-peer support, patient support programs). At the same time, patient organizations collaborate to scale patient and care partner education.



Vision Goal 2: Expand capacity and resources to deliver CAR T-cell therapy

Indicator

Number and geographical distribution of new CAR T-cell therapy treatment centers certified and actively treating patients each year.

Recommended actions

- Referring centers and treating centers build communication networks and partnerships, including regular meetings with regional hubs to agree on patient eligibility, referral, and prioritization. This should include the establishment of clear quality standards and responsibilities for referral to ensure a predictable and equitable pathway regardless of geography.
- Health system leaders, planners, and hospital administrators explore alternative delivery models to relieve bottlenecks and reduce patient travel, including decentralizing parts of the CAR T-cell therapy delivery and care pathway.
- Governments commit to publishing a five-year national advanced therapy medicinal products (ATMP) strategy that sets out capacity and forecast planning mechanisms, funding and investments, as well as service standards for patient identification, referral pathways, and funding mechanisms. At the same time, a working group with key stakeholders should be set up to oversee and monitor the national ATMP strategy.



Vision Goal 3: Develop sustainable and innovative financing approaches to manage the costs of treatment and care

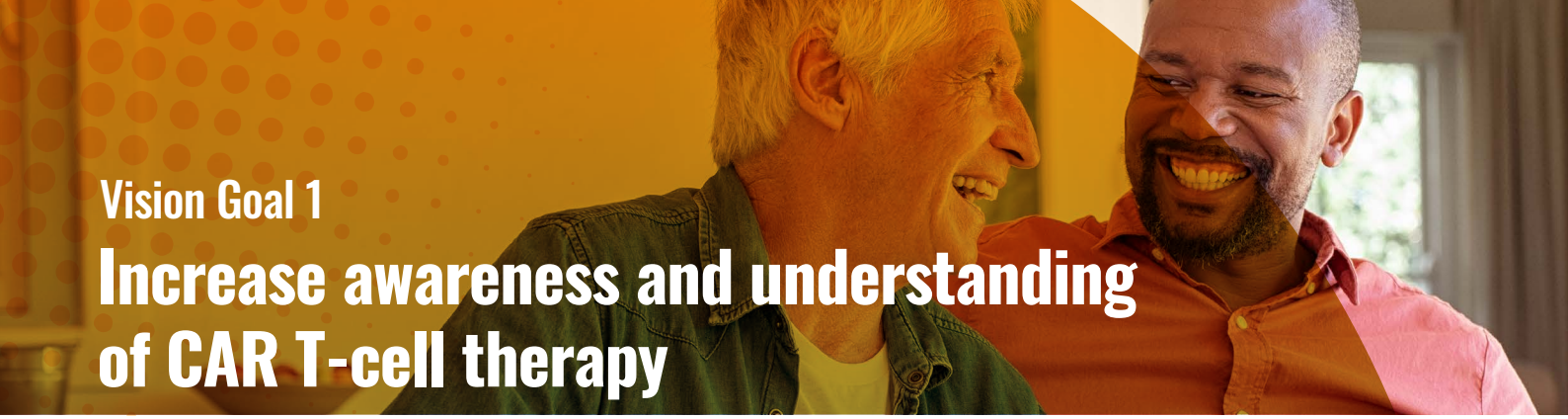
Indicator

Proportion of licensed CAR T-cell therapy products that are reimbursed, and time from regulatory approval to public reimbursement and commissioning in each country.

Recommended actions

- Regulators, HTA agencies, payors, and manufacturers coordinate to streamline decision-making from regulatory submission through to patient access, and to standardize real-world evidence requirements.
- Payors and health system budget holders commit to dynamic funding models that prioritize early industry engagement and allow for rapid adoption of newly approved therapies outside of the traditional annual budget cycle, potentially through ring-fenced innovation funds at the national or regional level.
- Health authorities, hospitals, and health insurance programs work together to ensure that there is sufficient funding for the delivery of CAR T-cell therapy. This could be through the creation of dynamic national tariffs and a dedicated diagnosis-related group (DRG) for CAR T-cell therapy that is regularly reviewed and adjusted based on rigorous and transparent health economic costing methodologies to calculate the cost of treatment delivery.

Double the proportion of eligible patients treated with CAR T-cell therapy by 2030.



Vision Goal 1

Increase awareness and understanding of CAR T-cell therapy

Barriers to Address

The uneven use of CAR T-cell therapy across Europe, and within individual countries, contributes to gaps in awareness and understanding, particularly around the therapy's efficacy and safety profile, eligibility criteria, referral processes, and the urgent need for timely referral.[1,2,5,6] Improving understanding among clinicians is essential to avoid delays in identifying and referring eligible patients. At the same time, patients and care partners need **clear, accessible information** on the benefits, risks, and practical considerations of CAR T-cell therapy so they can make **informed treatment decisions**.

Recommended Actions

How stakeholders can take forward this action (examples in practice included, where available):

Referring centers, treating centers, professional societies, and medical education providers collaborate on structured guidance, mentorship, and training programs to facilitate clinician understanding of patient eligibility, early patient identification, and referral processes.

Referral workshops, symposia, and multi-society educational programs can be hosted at key conferences and meetings for referring clinicians, treating clinicians, nursing staff, multidisciplinary teams (MDTs), and the hospital administrative team.

- *GoCART holds best practice sharing sessions for nurses and clinical case discussions for physicians.[7] Clinical cases are hosted on its website, alongside a Q&A to test knowledge and understanding.[8]*
- *The GoCART passport offers comprehensive digital modules, translated into five languages, on CAR T-cell therapy and its application.[9] This initiative could be expanded and integrated into professional training.*

Referring clinicians can be given opportunities to visit experienced CAR T-cell therapy treatment centers and observe the treatment process.

- *GoCAR T's Observership Program places early-career clinicians at established CAR T-cell therapy centers to support training and promote standardization in education and quality of care.[10]*

Treating centers can initiate outreach programs to their referral networks to increase education on patient eligibility, patient identification, and referral processes, while solidifying referral networks.

Professional societies, referring centers, and treating centers can develop a practical referral checklist with information on eligibility criteria, referral timing, and processes.

- *In spinal muscular atrophy, when gene therapies first became available, the community created readiness toolkits for clinicians that included clear eligibility checklists, urgent referral guidance, and family decision-making guides in plain language.*[11,12,13]

Hospitals can embed decision support into routine clinical workflows, such as standardized referral triggers or prompts linked to clinical criteria or lines of therapy within electronic health records, to help clinicians consider CAR T-cell therapy earlier.



Referring clinicians and treating clinicians provide patients and care partners with clear, accessible, and tailored resources early in the care pathway to support informed decision-making and address any concerns (e.g., decision aids, peer-to-peer support, patient support programs). At the same time, patient organizations collaborate to scale patient and care partner education.

Treating clinicians can provide patients and care partners with a written care plan early in their treatment journey to help them prepare for treatment requirements and plan appropriately.

Clinicians can direct patients and care partners to patient organizations such as Myeloma Patients Europe, Lymphoma Coalition,and International Myeloma Foundation, which offer accessible materials and guidance to help patients and care partners understand CAR T-cell therapy and the support that is available to them.[14,15,16]

Patient advocacy organizations can work with treating centers to develop a standardized guide for families moving between referring and treating centers, including what to expect at each stage, who to contact, what questions to ask, and how to prepare for treatment.

Patient advocacy organizations can collaborate with each other to consolidate and scale patient and care partner education, such as multilingual resources, pediatric resources, outreach initiatives, and peer support programs. Organizations can also work with T2Evolve Association (T2Evolve) to create and adapt visual informed consent resources.

Indicator to measure progress toward Vision Goal 1

Proportion of patients, care partners, referring clinicians, and multidisciplinary teams (MDTs) who feel well informed about CAR T-cell therapy and the referral process.

Goal 1 indicator will be measured by:

1. Patient, care partner, referring clinician, and MDT understanding of CAR T-cell therapy, including benefits, risks, treatment expectations, eligibility criteria, and referral processes.
2. Remaining gaps in information and knowledge among patients, care partners, non-treating clinicians, and MDTs.
3. Patients and care partners who feel empowered to participate in the decision-making process.
4. Referring clinicians who feel confident to provide the necessary information on CAR T-cell therapy to eligible patients and refer as appropriate.

To collect this data, the Vision will collate and audit existing surveys conducted by patient advocacy groups and professional societies to assess current levels of understanding and confidence in CAR T-cell therapy. The audit will be used to understand if there are gaps in data collection that could be filled by primary research in following years.





Vision Goal 2

Expand resources and capacity to deliver CAR T-cell therapy

Barriers to Address

The uneven geographical distribution of treatment centers across Europe often requires patients to travel long distances, creating financial and logistical barriers to access.[4] This is compounded by capacity constraints within treatment centers, including shortages of intensive care unit (ICU) beds, hospital apheresis slots, and trained staff, which can lead to further delays in treatment.[1,2,17] Health systems must be equipped to **meet both current and future demand for CAR T-cell therapy** and ensure that **more patients are able to access treatment closer to where they live.**

Recommended Actions

How stakeholders can take forward this action (examples in practice included, where available):

Referring centers and treating centers build communication networks and partnerships, including regular meetings with regional hubs to agree on patient eligibility, referral, and prioritization. This should include the establishment of clear quality standards and responsibilities for referral to ensure a predictable and equitable pathway regardless of geography.

In countries with devolved healthcare management, regional health networks can serve as a coordinating platform for referrals, eligibility decisions, and treatment prioritization for CAR T-cell therapy.

- *Catalonia, along with other regions in Spain, has established a well-defined hematology network, with small peripheral hospitals strongly connected to larger hospitals, which in turn each have a designated CAR T-cell therapy center to which potential patients are referred.*[1,3]
- *Certain regions in Italy have developed regional CAR T-cell therapy networks for centralized decision-making. The Emilia-Romagna region has established a regional network including centralized decision-making on patient eligibility and a waiting list for treatment.*[1,3,18]

In countries with more centralized or competitive, non-network-based systems, mandated referral partnerships between treating and non-treating centers can formalize coordination.

- *In the German region of Rhineland-Palatinate, CAR T-cell therapy treatment centers and larger hospitals collaborate in a competence network for cellular therapy. This includes holding weekly meetings to discuss patient cases and developing CAR T-cell therapy treatment criteria and pathways.*[1,3]
- *In the French region of Occitania, the regional hematology network led by the Centre Hospitalier Universitaire de Montpellier introduced a dedicated CAR T-cell therapy segment into its weekly multidisciplinary meetings to review all eligible patients and advise referring physicians on CAR T-cell therapy eligibility. They have also established clear pathways and quality criteria for the referral process, including a requirement that patient eligibility be confirmed within eight days of the committee discussion.*[1,3]

Health system leaders, planners, and hospital administrators explore alternative delivery models to relieve bottlenecks and reduce patient travel, including decentralizing parts of the CAR T-cell therapy delivery and care pathway.

Treatment centers (hubs) can collaborate with non-treating centers (spokes) to deliver parts of the CAR T-cell therapy pathway (e.g., apheresis, lymphodepleting chemotherapy, follow-up care) closer to patients' homes.

- *In France, specialized rehabilitation centers outside of treatment centers in Montpellier and Lyon offer patient monitoring and accommodation following CAR T-cell therapy infusion, which allows for increased bed capacity at treatment centers. Apheresis is expanded outside of treatment centers through collaboration with the French Blood Collection Association.*[1,3]
- *Toulouse University Hospital and the West Onco-Occitanie cancer network have been able to significantly reduce the length of hospital stays through a shared care model, in which lymphodepleting chemotherapy is provided by the referring center.*[1,19]
- *In Spain, leukapheresis for CAR T-cell therapy production is provided by certain specialized centers to improve bed capacity and reduce travel requirements for patients.*[1,3]

Delivery capacity can be expanded through existing specialist networks and infrastructure.

- *In the UK, the number of centers offering CAR T-cell therapy has expanded to include more allograft centers that have the right capabilities and infrastructure in place to deliver CAR T-cell therapy. Existing allograft networks also offer a referral pathway for CAR T-cell therapy.*[1,20]

Governments commit to publishing a five-year national advanced therapy medicinal products (ATMP) strategy that sets out capacity and forecast planning mechanisms, funding and investments, as well as service standards for patient identification, referral pathways, and funding mechanisms. Simultaneously, a working group with key stakeholders should be set up to oversee and monitor the national ATMP strategy.

In practice, national planning requires formal governance structures, engagement with local experts, and the establishment of data collection processes, goals, and targets to support decision-making.

- *In the UK, while there is no national ATMP strategy, an ATMP coordinating group exists to forecast and plan for anticipated increases in CAR T-cell therapy use, thereby relieving pressures on the system.*[1]
- *Germany published its national strategy for cell and gene therapies in June 2024, which includes goals around establishing interdisciplinary cell and gene therapy treatment centers.*[21]
- *As a result of France's National Cancer Plan, French authorities supported the development of referral partnerships and regional multidisciplinary committees in some French regions, such as Occitania and Auvergne-Rhône-Alpes.*[3,22]
- *In Europe, T2EVOLVE is developing tools to support national planning processes, allowing system planners to better support coordination and resource planning.*

Hospitals, health systems, and health authorities can work together to forecast resource needs to plan, secure, and allocate budgets in advance.

- *In collaboration with the regional health authority in Tuscany, Italy, Careggi University Hospital conducted an early assessment of its organizational and resource needs and secured additional funding for capacity needs.*[3,18]
- *Since 2018, Spain has had an established national ATMP strategy that undergoes regular reviews, titled "Plan para el Abordaje de las Terapias Avanzadas en el SNS." The plan tracks data at regional and national levels such as use of CAR T-cell therapy, time from referral to treatment, and distribution of centers to inform policymaking.*[23] *The plan is based on the principles of equity, safety and efficiency, with centralized authorization and registration of ATMPs and systemic collection of data to support their evaluation. Under the plan, the Spanish Ministry of Health increased the number of designated CAR T-cell therapy centers to several regions that did not have any centers to expand equitable access to treatment.*[24] *This planning has also been carried out at the regional level in Madrid in consultation with local experts to outline areas of focus.*

Indicator to measure progress toward Vision Goal 2

Number and geographical distribution of new CAR T-cell therapy treatment centers certified and actively treating patients each year.

Goal 2 indicator will be measured by:

1. Number of centers accredited by Joint Accreditation Committee of the International Society for Cell & Gene Therapy (JACIE) and/or qualified by manufacturers.
2. Number of centers actively treating patients.
3. Geographical spread of centers.

The Vision will use online databases from JACIE and European Society for Blood and Marrow Transplantation (EBMT), as well as ask CAR T-cell therapy manufacturers to provide relevant data. The Vision will also track other emerging models of delivery that expand access to CAR T-cell therapy, including academic institutions with the capability to provide CAR T-cell therapy in instances where no treatment options are available.†



† Academic institutions with localized manufacturing capability can offer CAR T-cell therapy through the legal basis of hospital exemption. This is used only in cases where there is an exceptional high unmet need and no other CAR T-cell therapy treatment options are available.



Vision Goal 3

Develop sustainable and innovative financing approaches to manage the costs of treatment and care

Barriers to Address

Variability in reimbursement frameworks and real-world evidence requirements, together with multiple stages of health technology assessment (HTA) for CAR T-cell therapy, leads to inconsistent timelines and delays in patient access across Europe.[5,25,26,27,28] As more CAR T-cell therapies become available in different indications, it is essential that **reimbursement and payor methodologies and processes keep pace with advances in science,** and that new therapies reach eligible patients without additional delays.

Recommended Actions

How stakeholders can take forward this action (examples in practice included, where available):

Regulators, HTA agencies, payors, and manufacturers coordinate to streamline decision-making from regulatory submission through to patient access, and to standardize real-world evidence requirements.

Early alignment of processes, use of access pathways prior to full reimbursement, and cross-system collaboration mechanisms enable coordination, speedier decision-making, and access.

- *In Spain, an outcomes-based agreement has been introduced with two payments occurring after treatment administration and based on treatment response.*[3,27]
- *In France, CAR T-cell therapies have been introduced through the 'temporary authorization for use' early access program prior to European Medicines Agency (EMA) marketing authorization, enabling treatment in specialized centers with support from regional health authorities. This mechanism allows patients with high unmet needs to access treatment while real-world data is collected through national registries to support the transition to statutory reimbursement. This collaboration is expected to continue for new CAR T-cell therapy indications under the National Cancer Plan.*[1,3]
- *The Beneluxa Initiative and the Nordic Pharmaceutical Forum demonstrate how cross-country collaboration can support more consistent and timely access to innovative medicines. These initiatives bring together national authorities to coordinate activities such as horizon scanning, joint HTA, joint price negotiations, and collaborative procurement.*[29,30]

Stakeholders can engage with the European network of Centres of Excellence (CoEs) for ATMPs as it develops its policy recommendations, bringing practical experience of CAR T-cell therapy assessment, evidence generation, and reimbursement to its discussions.[31]

Stakeholders can engage with T2Evolve on its data collection initiatives that seek to explore ways in which data can be harmonized and aligned across clinical care, regulatory assessment, HTA, and reimbursement.



Payors and health system budget holders commit to dynamic funding models that prioritize early industry engagement and allow for rapid adoption of newly approved therapies outside of the traditional annual budget cycle, potentially through ring-fenced innovation funds at the national or regional level.

In the UK, NHS England moved quickly and decisively to launch CAR T-cell therapy with the first approved product receiving funding 10 days after EMA marketing authorization. The National Institute for Health and Care Excellence (NICE) recommended CAR T-cell therapies through the Cancer Drugs Fund, which allowed patients to access these innovative treatments while additional data on their clinical and cost-effectiveness was collected.[1,20] The opportunity provided by NHS England for engagement prior to licensing was key to facilitating early conversations about launch and access, ultimately expediting the process.

In Italy, the national medicines regulatory body, Agenzia Italiana del Farmaco (AIFA), has awarded CAR T-cell therapies "innovative" status, which led to funding through the national fund for innovative oncology drugs (Fondo per i Farmaci Innovativi Oncologici) and their inclusion in formularies. The upfront cost of the therapy is paid in three pre-specified installments over a 12-month period.[18,32]



Health authorities, hospitals, and health insurance programs work together to ensure that there is sufficient funding for the delivery of CAR T-cell therapy. This could be through the creation of dynamic national tariffs and a dedicated diagnosis-related group (DRG) for CAR T-cell therapy that is regularly reviewed and adjusted based on rigorous and transparent health economic costing methodologies to calculate the cost of treatment delivery.

Indicator to measure progress toward Vision Goal 3



Proportion of licensed CAR T-cell therapy products that are reimbursed, and time from regulatory approval to public reimbursement and commissioning in each country.

Goal 3 indicator will be measured by:

1. Time from EMA or Medicines and Healthcare products Regulatory Agency (MHRA) approval to HTA decision.
2. Time from HTA decision to formulary inclusion and patient access.[±]
3. Number of CAR T-cell therapy products licensed compared with the number reimbursed and commissioned.

To collect this data, the Vision will track reports published by EMA, MHRA, and HTA agencies, alongside the reasons for any delays.

[±] A CAR T-cell therapy product is considered available when patients can access it through a routine or nationally recognized funded pathway.



Role of CAR T Vision Coalition in supporting the implementation of the Blueprint

The **CAR T Vision coalition provides leadership and convening power** to support, coordinate, and facilitate the implementation of the recommended actions and indicators. The Vision does not seek to supplant existing initiatives, but rather to build on and complement ongoing efforts and provide a focal point for stakeholders to come together. Working in partnership with stakeholders, the Vision will consolidate case studies, promote best practice sharing, facilitate knowledge exchange, and develop resources where none currently exist.

Reach out to the CAR T Vision Secretariat at **visionforcart@incisivehealth.com** to find out more about how you can get involved, implement the Vision in your locality, and contribute case studies to spotlight local initiatives or datasets to support measurement.

What is the Vision doing?

Convening multistakeholder groups
to advocate for increased capacity, resources, and access to CAR T-cell therapy.

Collaborating with GoCART and T2EVOLVE Association
to complement ongoing efforts to improve access to CAR T-cell therapy.

Establishing a baseline against the European indicators
in 2026 across the UK, Spain, Italy, Germany, and France, and measuring progress annually beginning in 2027.

Providing the Vision to Action Toolkit
to support in-country implementation of the Vision.

Developing a central hub of resources,
including guidance, toolkits, and case studies on CARTVision.com for inspiration and reference.

Elevating best practices
at key European and global events, and through the Vision's communication channels.



Acknowledgements

The recommendations in this document reflect the **collective insights of the CAR T Vision Steering Committee as well as an expert group** in the field of CAR T-cell therapy. The expert group provided input through meetings and Delphi surveys. These recommendations are not to be interpreted as endorsements by the organizations that individuals are affiliated with.

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