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CAR T-cell therapies in Germany

Overview of political fields of action for better patient access

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About this study

This study was conducted by PwC Strategy& on behalf of Gilead Sciences. The results are based on 18 interviews with experts who gather experience with CAR T-cell therapies in their daily work, including hematologists at CAR T centers, medical controllers and representatives of major public health insurance companies. All interviews were conducted on the basis of a standard questionnaire in which the experts were asked about their experience with CAR T-cell therapies, practical hurdles and proposals for possible solutions. All interviews were conducted anonymously.

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EXECUTIVE SUMMARY

Precision medicine promises to achieve significant improvements in healthcare provision by personalizing medical prevention, diagnostics and therapy as well as novel options for the treatment of patients, while at the same time driving long-term cost savings.[1]

Since 2018, oncologists in Germany have had access to innovative, personalized *chimeric antigen receptor T-cell therapies* (CAR T-cell therapies), which offer critically ill cancer patients the potential chance for cure.[2] However, since their launch in the German market in August 2018, in clinical practice, CAR Ts seem to have reached only a small portion of eligible patients.[3] Based on approx. 20 interviews with experts from different functions of the German healthcare system, this paper presents an analysis of principal hurdles to patient access and derives potential specific political fields of action to improve healthcare provision.

CAR T-cell therapies are classified as *Advanced Therapy Medicinal Products* (ATMP), which are drugs derived from genes, cells or tissue.[4] Currently, CAR Ts are being prescribed as a last, non-palliative treatment option for patients who have not responded to multiple previous therapies (see "Background"). Thus, a timely CAR T therapy may be essential for patients[5] who otherwise have an average survival period of around 6 months.[6] Yet, only few eligible patients in Germany currently seem to receive access to these therapies.

The reasons behind this are diverse and primarily driven by:

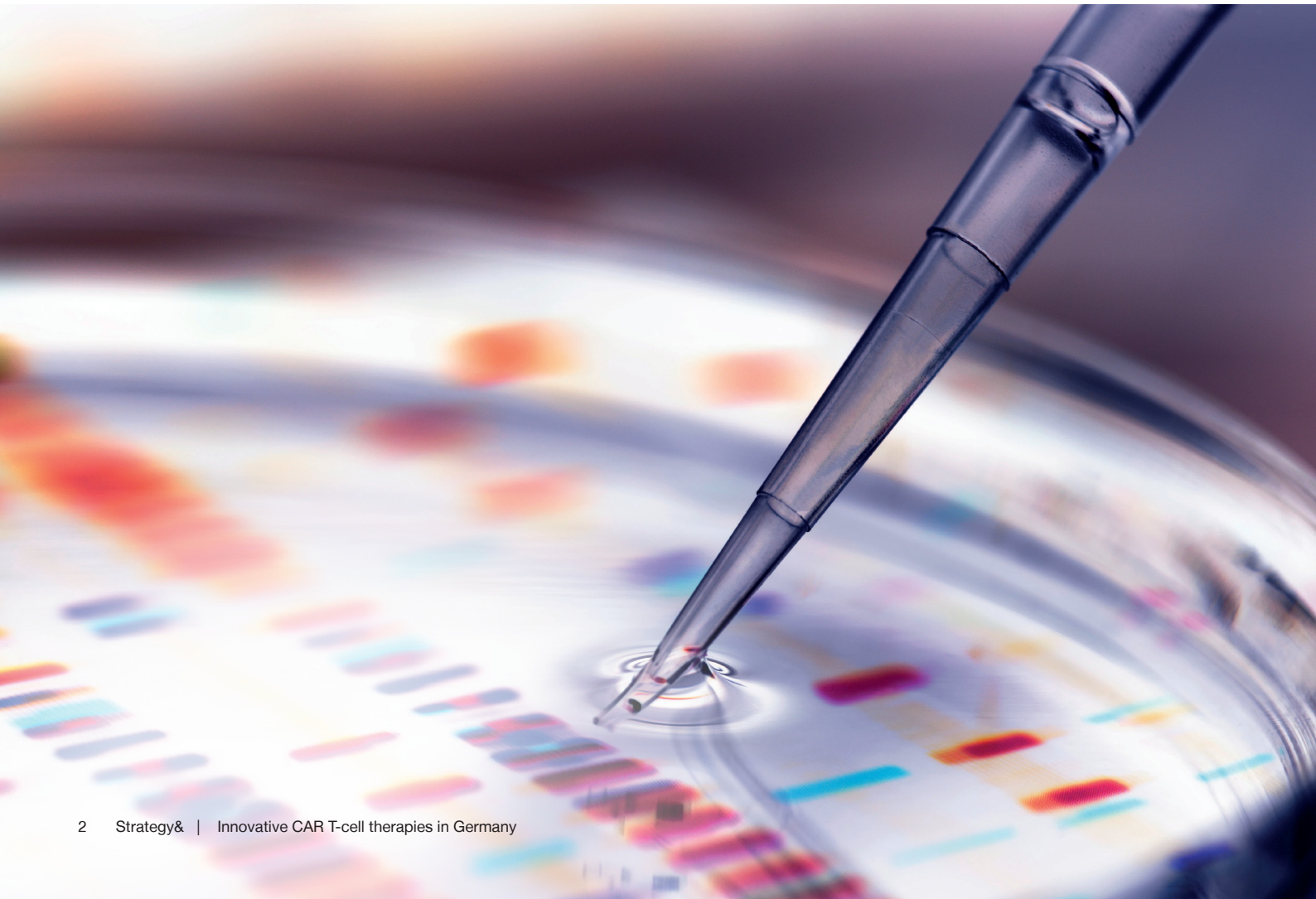
- Inconsistent levels of knowledge about these innovative cancer therapies
- Insufficient clarity regarding the patient profile
- Nationwide heterogeneous standards and processes
- Lack of mechanisms for the management of financial risks of the CAR T center in charge, and
- Currently insufficient opportunities both for scaling and for systematic exchange.

1 Strategy&, Capitalizing on Precision Medicine 2017.
2 For these indications: Diffuse large B-cell lymphoma (DLBCL), primary mediastinal large B-cell lymphoma (PMBCL) und transformed follicular lymphoma (TFL), as described by Locke et al. Lancet Oncol 2019;20: 31–42, https://www.ncbi.nlm.nih.gov/pubmed/30518502.
3 Expert interviews. G-BA Definition for adult DLBCL und PMBCL third-line therapy candidates.
4 European Medicines Agency. Advanced therapy medicinal products: Overview https://www.ema.europa.eu/en/human-regulatory/overview/advanced-therapy-medicinal-products-overview.
5 Locke et al. Lancet Oncol 2019, DOI: 10.1016/S1470-2045(18)30864-7.
6 Average survival period for DLBCL patients – Crump et al. Blood 2017, DOI: 10.1182/blood-2017-03-769620. PwC Strategy& Interviews with oncologists and hematologists from CAR T centers.

With a view on the numerous ATMPs currently under development, these hurdles entail the risk of Germany falling behind other countries in terms of availability and application of these innovative therapies. To counteract this risk, we see the following fields of action (*see Exhibit 1, page 3*):

- Education towards and creation of an innovation-friendly climate
- Adjustment of qualification and funding processes
- Enabling scalability through centralization and uniform standards
- Further development and implementation of innovative payment models
- Fostering the exchange of practical experience

So that these innovative treatment options for seriously ill patients can further develop their potential, it is advisable for both the healthcare players involved and the political stakeholders to jointly campaign for an understanding of ATMPs that is open to innovation, dismantle existing systemic hurdles in a sustainable and pragmatic approach, and shape the German healthcare system to become more flexible, agile and efficient with regard to future innovations. CAR T-cell therapies – as a precedent – therefore offer an opportunity for political decision-makers to establish sustainable innovation structures in Germany.



Potential political fields of action

The following fields of action can potentially address the challenges (*see Exhibit 1*):

EXHIBIT 1
The following fields of action provide approaches to solving the challenges

Political levers	Examples of specific measures
1. Public awareness and innovation-friendly climate	• **Information campaigns** to promote innovative cancer therapies • Inclusion of cell therapies into **Continuing Medical Education** curricula
2. Qualification and funding processes	• **Cross-hospital NUB (Neue Untersuchungs- und Behandlungsmethoden = Novel Diagnostics and therapeutic methods) applications** • **Quarterly update** of NUB status and funding level • Near-term establishment of **Diagnosis-Related Groups (DRG)**
3. Scalability through centralization and uniform standards	• Implementation of **scalable mechanism** for the introduction and roll out of innovative therapies • **Harmonization of guidelines** for the qualification and funding of CAR T centers
4. Innovative payment models	• **Cost-benefit quantification** comparing CAR T to standard therapies • **Establishment of pay-for-performance pricing models** • **Risk-sharing system** to **distribute financial risks** across several partners
5. Exchange of practical experience	• **Nationwide expert committees** as exchange forums • **Definition of best practices** for healthcare providers, payers and manufacturers • **Systematic evaluation** of qualification and financing procedures

Source: Strategy& analysis

1. Raising public awareness and promoting an innovation-friendly climate towards cell and gene therapies

Current knowledge gaps around ATMPs and CAR T-cell therapies, respectively, can be closed by providing objective information both within the medical community and to the general public. This can potentially be achieved by launching an information campaign, for example in the context of the "National Decade Against Cancer" supported by the German Federal Ministry of Education and Research. Creating a higher degree of transparency and interaction among the stakeholders involved would also be beneficial, especially with regard to creating a common understanding of the patient profile. Likewise, regular updates of clinical guidelines by experts and reinforcement of guideline-driven therapy decisions are essential. In addition, nationwide expert groups (e.g. national tumor boards) could serve as platforms for sharing insights on innovative cancer therapies.

2. Adaptation of the qualification and funding process of CAR T centers

To enable fast access to ATMPs, adjustments to the AMNOG (the central process to assess therapeutic benefits of new drugs) as well as additional flexibility in securing the funding of CAR T centers (e.g., adjusting the NUB, ZE or DRG[7] process) could be helpful. Specific flexibility levers within the scope of the NUB process can include: A) the possibility to submit the NUB application centrally / across several eligible hospitals, B) the possibility to update the NUB status on a quarterly basis, C) the possibility to adjust the funding amount once per quarter based on actual cost data points, D) shorter decision periods (currently at approx. 3 months), and finally, E) an expedited establishment of DRGs.[8]

3. Scalability through centralized and uniform standards

Innovative approaches to therapy (such as, for instance, ATMPs) could be tested under everyday conditions by means of agile and efficient pilots and rolled out. To enable such effective deployment, a standardized, centralized and scalable mechanism will be essential which can also be used for future innovations. The new *Law for More Safety in the Supply of Pharmaceuticals* ("Gesetz für mehr Sicherheit in der Arzneimittelversorgung – GSAV") stipulates that quality guidelines and process design for ATMPs be developed jointly by the Federal Joint Committee ("Gemeinsamer Bundesausschuss – G-BA") and the Medical Service of the Health Insurance Funds ("Medizinischer Dienst der Krankenversicherung – MDK"), thus strengthening the influence of central authorities.[9] Furthermore, it is proposed that, in the first step, quality-related aspects in the benefit assessment decisions around ATMPs become part of independent quality guidelines.

4. Further development and implementation of innovative reimbursement models

The costs of CAR T-cell therapies are currently borne directly by the CAR T centers, which exposes them to financial risk. Options for innovative reimbursement models that allow this risk to be distributed and strengthen the partnership among stakeholders, respectively, could be tested and investigated. Alternative pricing models should ultimately aim to simplify patient access to therapy and to improve patient care.

5. Fostering the exchange of practical experience

All stakeholders, including, among others, manufacturers are gaining practical experience with CAR T centers in different regional and structural contexts. A systematic approach to collecting, reviewing or analyzing these insights as well as defining and reinforcing best practices in collaboration with healthcare providers and payers could serve as an important learning lever.

7 NUB – "Neue Untersuchungs- und Behandlungsmethoden" (New Examination and Treatment Methods) – are funds for recently introduced therapies that cannot be directly reimbursed via the DRG system.
ZE – "Zusatzentgelt" (Supplementary Funding) – additional per-case flat-rate payment for hospital services provided as inpatient treatment.
DRG – Diagnosis-Related Group – flat-rate reimbursement system for inpatient hospital services.
8 "Verband der Universitätskliniken Deutschlands" (Association of University Clinics in Germany), Expert Team "Gene and Cell Therapies". Presentation, 01.07.2019 on "Reimbursement in the inpatient sector for treatments with ATMPs / "NUB gap".
9 Federal Ministry of Health – "Gesetz für mehr Sicherheit in der Arzneimittelversorgung – GSAV" (Law for More Safety in the Supply of Pharmaceuticals) https://www. bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/Gesetze_und_Verordnungen/GuV/G/GSAV_GE_Kabinett.pdf

Background

Advanced Therapy Medicinal Products

ATMPs are novel therapies based on genes, cells or tissues. CAR T-cell therapies belong to this class of drugs and offer an innovative and promising treatment option for cancer patients with little non-palliative treatment options.[10]

On the German market, currently, CAR T-cell therapies from two manufacturers are approved for adult patients diagnosed with relapsed or refractory diffuse large B-cell lymphoma (DLBCL, both products) and primary mediastinal large B-cell lymphoma (PMBCL, Axicabtagene-Ciloleucel) after two or more lines of systemic therapy. Furthermore, one CAR T product is indicated for the treatment of pediatric and young adult patients up to and including 25 years of age with B-cell acute lymphoblastic leukemia (ALL), in post-transplant relapse or in second or later relapse (Tisageneleucel).

Clinical experience with ATMP available today indicates that some ATMPs can produce long-term – potentially even curative – therapeutic outcomes[11], thus eliminating the need for multiple or lifelong treatments with additional drugs.[12] Possible cost savings due to this, however, need to be determined.

Cell and gene therapies are not just another important milestone in the treatment of illnesses that so far have been not or not sufficiently treatable. They have also changed therapy management and partially require new processes. Close and interdisciplinary cooperation of medical experts from different specializations is a requirement for a successful CAR T-cell therapy. In order to effectively map such complex therapy schemes, specifically certified centers have proven useful. Early establishment of the required framework is necessary.

It can be assumed that the number of approved ATMPs will rise in the future, and that additional applications will be employed (e. g. CAR T-cell therapies as a second-line therapy), and that it will be possible to treat further indications (e. g. CAR T-cell therapies against multiple myeloma, solid tumors) and additional diseases (e. g. hemophilia) with ATMPs. Accordingly, the numbers of patients that may benefit from ATMPs will grow as well.[13]

Introduction of ATMP on the German market and successful treatments

Since 2015, eight ATMPs – mostly gene therapies – have been approved for use in the European healthcare market.[14] Other ATMPs, some already approved in the US, are currently under review by the European Medicines Agency (EMA).[15]

Since CAR T-cell therapies were approved in Europe in August 2018, the first patients in Germany have received a CAR T-cell therapy in centers especially qualified for such treatment. Initial reports of treating physicians along with patient statistics[16] indicate positive outcomes.

10 Deutsche Gesellschaft für Hämatologie und Medizinische Onkologie. Oncopedia – DLCBL. Diffuses großzelliges B-Zell-Lymphom. [*German Society for Hematology and Medical Oncology. Oncopedia – DLCBL. Diffuse large cell B-cell lymphoma.*] https://www.onkopedia.com/de/onkopedia/guidelines/diffuses-grosszelliges-b-zell-lymphom.
11 Zheng et al. (2020). Efficacy and safety of chimeric antigen receptor-T cells in the treatment of B-cell lymphoma: a systematic review and meta-analysis.
12 Locke et al Lancet Oncol 2019 doi: 10.1016/S1470-2045(18)30864-7.
13 Eder, C. & Wild, C. (2019) Technology forecast: advanced therapies in late clinical research, EMA approval or clinical application via hospital exemption.
14 Ibid.
15 European Medicines Agency (2020). Medicines under evaluation.
16 Locke et al. Lancet Oncol 2019, doi: 10.1016/S1470-2045(18)30864-7. PwC Strategy& interviews with oncologists and hematologists at CAR T centers.

The manufacturing and provision of CAR T-cell therapies on the German market are the result of close cooperation between manufacturers, regulatory agencies and CAR T centers. The latter are competence centers, mostly located in university hospitals, which need to be highly specialized in order to comply with the complex requirements of the regulatory agencies.

To date, 16 of these centers have been qualified for treatment with Axicabtagene Ciloleucel nationwide, which includes the establishment of special infrastructure, medical procedures and team competencies. Moreover, first treatment networks are already being established, where CAR T centers act as competence centers for patient care, providing a platform for the exchange of information and experiences, and helping to establish CAR T-cell therapies as a treatment method in their geographical region.

Following the completion of the early benefit assessment (AMNOG process) in fall 2019 and additional negotiations between CAR T manufacturers and the German public payer association, GKV-SV, the reimbursement price for the two CAR T therapies was set at 275k €[17] and 282k €[18] per treatment, respectively.

Current hurdles and their implications

To date, the established political and regulatory CAR T framework seems to have successfully addressed many challenges from the qualification and certification of treatment centers up to the price-setting mechanism for ATMPs through the AMNOG process. However, despite access to this type of therapies in Germany has basically been ensured, CAR T-cell therapies are still being integrated rather slowly into clinical practice (*see Exhibit 2, page 7*).

On the basis of the expert discussions conducted in the context of this study, we have identified five major hurdles that make it complicated to use CAR T-cell therapies in practice:

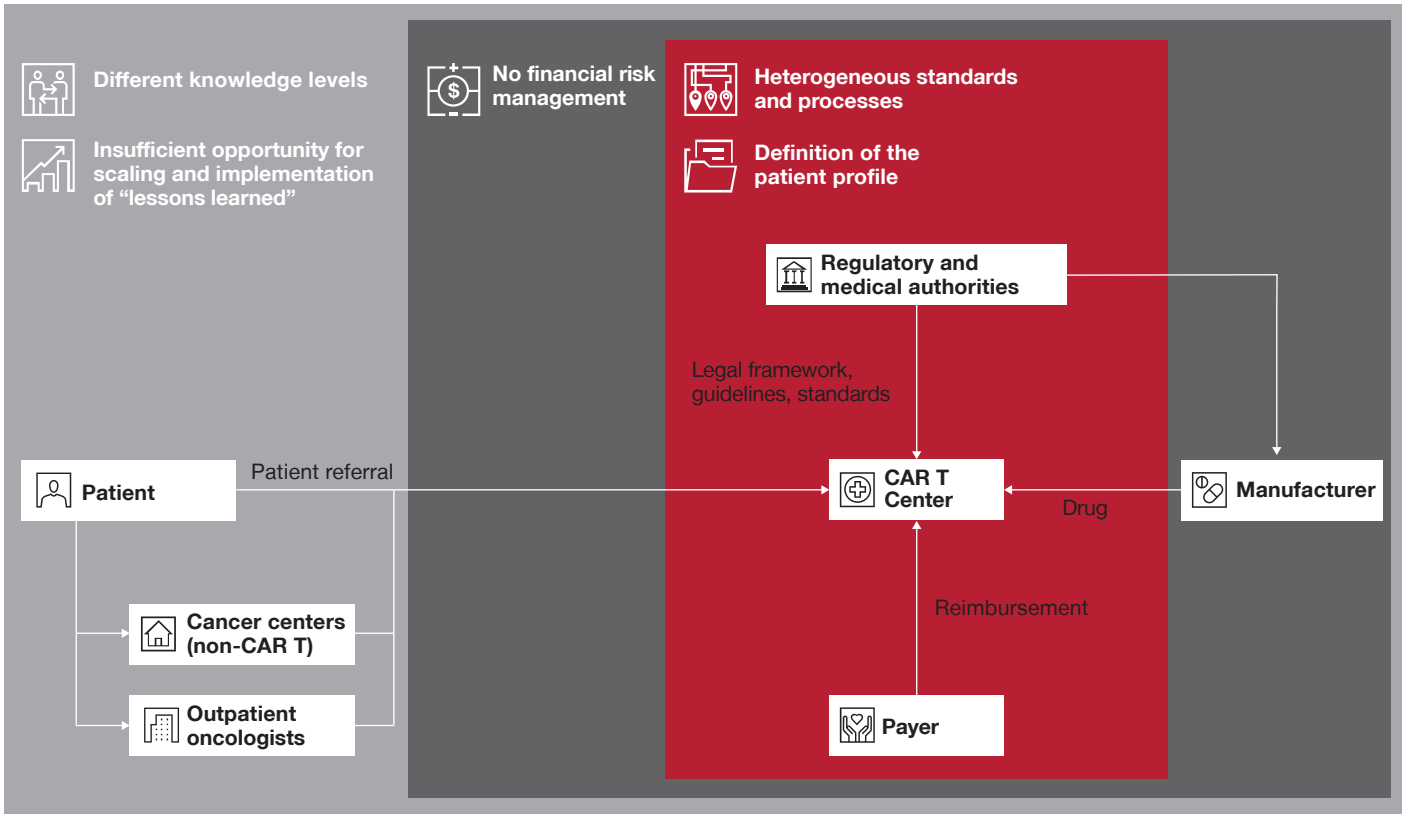
- **Inconsistent knowledge and level of awareness**. At present, physicians at specialized CAR T centers are the primary ATMP knowledge holder. Physicians at non-qualified cancer centers or in outpatient practices still refer comparably few patients to qualified CAR T centers. The reason for this can probably be explained by the lack of incentives, insufficient knowledge about CAR T-cell therapies, and a lack of active communication from CAR T centers to potentially referring doctors from other institutions. Even health insurance companies do not seem to have uniform processes for dealing with innovative therapies. Therefore, not all patients are informed in equal measure regarding the availability of this treatment option and the opportunities it provides.

- **Definition of the patient profile**. Although the patient profile for patients eligible to receiving CAR T therapy is defined by the summary of product characterization and clinical guidelines by the German Society for Hematology and Medical Oncology, respectively, the limited practical experience among providers and payers may cause disagreement as to whether or not a patient is eligible for treatment. This is especially true in case of pre-existing comorbidities which are not explicitly described in the summary of product characteristics ("Fachinformation") or have been explicitly considered to be exclusion criteria in previous registration trials, respectively. The high administrative effort involved in clarifying decisions can lead to significant delays in treatment, which may ultimately have negative effects on the treatment success or, in extreme cases, lead to patients being denied the treatment they would have been eligible for. Until a mutual agreement on the handling of comorbidities has been established, some patients may be de facto refused CAR T-cell therapies for formal – but not necessarily for medical – reasons.

17 Ärtze Zeitung (2019).
18 Deutsche Apotheker Zeitung (2019).

- **Heterogeneous standards and processes for treatment center qualification and reimbursement across federal states.** Whether or not – and when – a patient receives a CAR T-cell therapy currently depends not only on the medical expertise of the treating physician but also on a multitude of factors, such as the efficiency of the interaction between the respective CAR T center and the local medicinal authorities and payers, respectively. In the absence of uniform standards (e.g. standard operating procedures, binding deadlines), processes for providing CAR Ts are being established with a high degree of variability across German federal states and payer organizations. Consequently, comparable tasks and processes, such as CAR T center qualification, are addressed via individual solutions and timelines. The wide range of standards and processes, however, creates uncertainty for patients as to whether or not and when a CAR T-cell treatment will be applicable and possible for them. For example, patients of large, public payers are likely to benefit from a better administrative set up with regard to managing access to innovative therapies.

EXHIBIT 2
Overview of key systemic hurdles and affected stakeholders



Source: Strategy& analysis

- **Insufficient financial risk management for CAR T centers**. Patient access to CAR T-cell therapies is currently strongly dependent on the economic situation of the treating CAR T centers (including the availability of a dedicated ATMP budget, the volume of negotiated NUB contracts, or the procurement process for certain parts of the CAR T-cell therapy treatment, e.g. apheresis). The reason behind this is that CAR T centers are currently the principal carriers of financial risks. Should actual treatment costs exceed the negotiated NUB limit, or should payers deny or withdraw reimbursement for a completed CAR T therapy, it is the CAR T center that bears the financial responsibility. As a result, CAR T centers face the challenge of ensuring the provision of innovative, life-saving therapies while, at the same time, having to manage the financial risk involved. It cannot be ruled out that this dilemma – at least as long as no DRGs are established – will continue to influence or even limit the number of prescribed CAR T-cell therapy treatment.

- **Insufficient opportunity for scaling and routine exchange of "lessons learned."** To our knowledge, there is currently no central organization that monitors, evaluates or adjusts the speed and success of the adoption of ATMPs in Germany, or could standardize key processes across the German federal states. Practical experience is currently gathered locally by individual CAR T centers or manufacturers, and sporadically shared via established networks. In addition, it is still uncertain whether the existing processes will have to be repeated in a similar or improved form when therapies are introduced for further indications. Without mechanisms for a comprehensive and systematic exchange and the implementation of "lessons learned", there is a risk that errors and inefficiencies will be replicated. This risk impairs systemic scalability, which will be an essential requirement for future integration of new CAR T-cell therapies and other ATMPs.

These hurdles must be viewed critically in the context of the German healthcare system as this is where Germany differs from other neighboring EU countries. A relevant aspect in this context is the organization principle of the federal healthcare system. In Germany, where it is left to health insurers, service providers and contributors to organize themselves nationally and regionally within the legislative framework, the introduction of CAR T-cell therapies takes place via processes that differ from region to region.

Increased stakeholder cooperation to develop flexible and pragmatic solutions that are in the best interest of patients could potentially promote equal nationwide market access for CAR T-cell therapies. The development of a systemic solution will certainly take time and requires the close and trusting cooperation of medical and political stakeholders. Political stakeholders can contribute a great deal by setting the legal course and by playing a coordinative and mediating role. The various stakeholders can benefit from the experience gained so far in order to jointly address acute challenges in a solution-oriented manner in the interest of the patients' well-being. In this way, the German health system can be prepared for the future and pave the way for further innovative cell and gene therapies.

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