HPR80

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Managed entry agreements for cell and gene therapies in Germany: current landscape and possible mitigation strategy for Most-Favored-Nation (MFN) pricing

Background

- Managed Entry Agreements (**MEAs**) between manufacturers and payers enable access to health technologies under specific conditions.
- New pharmaceuticals in Germany are generally reimbursed upon marketing authorisation.
- The freely set launch price is reimbursed with product launch (§ 31 (2) SGB V)[1].
- The negotiated reimbursement price applies from month 7 after launch (§ 130b (3a) SGB V)[1].
- The reimbursement price is publicly listed; confidentiality is only possible when fulfilling defined criteria under § 130b (1c) SGB V and additional 9 % discount, until 30 June 2028[1].
- US **Most-Favored-Nation (MFN)** pricing (EO 14297) references the second lowest price in comparable OECD countries incl. Germany[2].
- Innovative contracting is proposed as a key mitigation strategy.

Objectives

- Identification of existing MEAs for CGTs in Germany.
- Examine the rationale underlying these agreements.
- Characterise the different types of MEAs.
- Assess relevant aspects in the context of MFN pricing.

Methods

- Systematic researches in **GBA** and **GKV-SV** databases and the official price database (**Lauer-Taxe**); data cut-off June 2026.
- Hand searches of **press releases** and **arbitration board decisions.**
- Classification: **risk-sharing** vs. **performance-based** MEAs.

Results

Five of 16 CGTs available in Germany are subject to an identifiable MEA – all performance-linked

As of June 2026, 16 EMA-approved CGTs were available in Germany. For five of them (31%) MEA were identified. Agreements were concluded either selectively between the manufacturer and individual health insurance companies (Yescarta®) or their contracting service providers (Kymriah®, Zolgensma®) or at national level with the GKV-SV as part of the reimbursement agreement (Imlygic®, Hemgenix®).

16
EMA-approved CGTs available in Germany (06/2026)

5 (31%)
CGTs with identifiable MEA

3 | 2
risk-sharing | performance-based agreements

Table 1: *CGTs with identifiable MEAs in Germany (status: June 2026)*

Product (INN) · MAH	Modality	Indication at EU approval	EU approval	MEA in Germany (type · partner · year)
Imlygic® *talimogene laherparepvec* Amgen	Oncolytic HSV-1 (GTMP); intralesional, repeated	Unresectable melanoma, regionally or distantly metastatic (stage IIIB–IVM1a) without bone, brain, lung or other visceral disease	12/2015	**Performance-based** · linked to treatment duration · national model with GKV-SV · 2017[3]
Kymriah® *tisagenlecleucel* Novartis	Autologous anti-CD19 CAR-T; single infusion	r/r B-ALL (≤ 25 years); r/r DLBCL after ≥ 2 lines of systemic therapy	08/2018	**Risk-sharing** · partial refund if patient dies of the disease within a defined period · GWQ Service Plus · 2019[4]
Yescarta® *axicabtagene ciloleucel* Kite / Gilead	Autologous anti-CD19 CAR-T; single infusion	r/r DLBCL and PMBCL after ≥ 2 lines of systemic therapy	08/2018	**Risk-sharing** · rebates linked to individual patient outcome[5] · DAK-Gesundheit · 2019
Zolgensma® *onasemnogene abeparvovec* Novartis Gene Therapies	In vivo AAV9 gene therapy; single i.v. infusion	5q SMA with bi-allelic SMN1 mutation and clinical SMA type 1, or up to 3 SMN2 copies	05/2020 (conditional)	**Risk-sharing** · outcome-oriented reimbursement · GWQ and PKV · 2020[6]
Hemgenix® *etranacogene dezaparvovec* CSL Behring	In vivo AAV5 gene therapy; single i.v. infusion	Severe and moderately severe haemophilia B (adults) without history of FIX inhibitors	02/2023 (conditional)	**Performance-based** · national model with GKV-SV · reimbursement linked to individual treatment success · 2025[7]

AAV: *adeno-associated virus;* B-ALL*: B-cell acute lymphoblastic leukaemia;* CAR-T: *chimeric antigen receptor T-cell therapy;* DLBCL: *diffuse large B-cell lymphoma;* FIX: *factor IX;* GTMP: *gene therapy medicinal product;* HSV-1: *herpes simplex virus type 1;* INN: *International nonproprietary name;* MAH: *marketing authorisation holder;* PMBCL: *primary mediastinal large B-cell lymphoma; r/r: relapsed/refractory;* SMA: *spinal muscular atrophy*

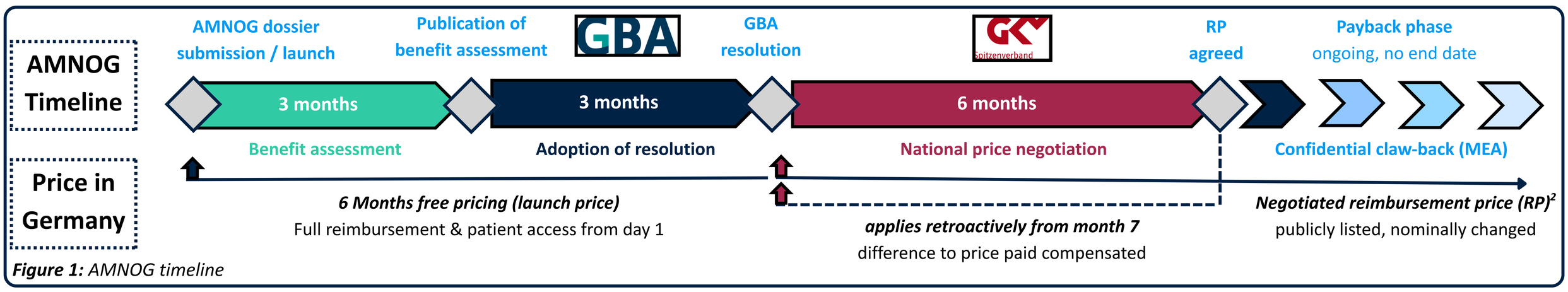


Figure 1: *AMNOG timeline*

Conclusion

- 31% (5/16) of CGTs available in Germany are subject to MEAs, all performance-linked and concentrated among high-cost therapies.
- In the context of MFN pricing, MEAs can only serve as an effective mitigation strategy if the statutory reimbursement price remains nominally unchanged and the agreement incorporates a claw-back mechanism, ensuring confidential rebates do not trigger reference pricing obligations in other markets.
- Faster availability of claims data from statutory health insurers could further enhance the feasibility of such arrangements.
- Germany's existing MEA infrastructure may offer a replicable template, provided the structural prerequisites are met.

References

1. Social Code Book V (SGB V), §§ 31, 35a, 130a, 130b, 130c
2. Executive Order 14297, 12 May 2025
3. Arbitration board decision, 22 September 2017 (Imlygic®)
4. Deutsches Ärzteblatt, 06 March 2019 (Kymriah®, GWQ)
5. Pharmazeutische Zeitung, 11 June 2019 (Yescarta®, DAK)
6. Deutsche Apotheker Zeitung, 24 April 2020 (Zolgensma®, PKV/GWQ)
7. CSL Behring press release, 02 April 2025 (Hemgenix®)

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Abbreviations

AMNOG: Act on the reorganization of the pharmaceutical market; CGT: cell and gene therapy; GBA: Federal joint committee; GKV-SV: National association of statutory health insurance funds; MEA: Managed entry agreement; MFN: Most-Favored-Nation; PKV: Private health insurance

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