

Negotiating drug prices without restricting patient access: lessons from Germany

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In the ongoing conversation about high drug prices in the United States, some loud voices argue that the solution is to allow Medicare to negotiate prices directly with manufacturers. The [Congressional Budget Office](#)² and others say this would lead to the exclusion of some drugs from coverage, require physicians to obtain prior authorization more often than they already do, and impose more cost sharing on patients — strategies that would keep patients from accessing medications they can benefit from.

That doesn't have to be the case. Germany's approach to negotiating drug prices shows that it can be done successfully without limiting access.

The health insurance and pharmaceutical purchasing system of Germany builds on 110 health plans, referred to as [sickness funds](#)³, that cover health expenses for 90% of the population, plus 48 indemnity insurers, who cover the remainder. As we wrote [in the journal Health Affairs](#)⁴, these funds collectively negotiate prices with drug manufacturers. The negotiations, conducted after a drug has received market authorization by the European Medicines Agency (EMA), are based on an assessment of the clinical benefit offered by the new drug compared to treatments already in use.

The clinical assessments are conducted and commissioned by a federal committee called the Gemeinsamer Bundesausschuss (G-BA), a quasi-public entity governed by the national associations of physicians, dentists, hospitals, sickness funds, and patient advocates. A statutory principle of the German system is that there will be no incremental price without incremental benefit. The G-BA's assessments are based on patient-relevant clinical endpoints such as overall survival, functional ability, and reduction in symptoms, rather than on intermediate endpoints such as reduced tumor size or a change in biomarker levels.

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Once the umbrella organization of sickness funds negotiates the price of a drug, the manufacturer is prohibited from unilaterally raising the price in subsequent years. Prices can be adjusted over time only if the G-BA conducts a new comparative effectiveness analysis, followed by a new round of negotiations.

All health plans pay the same collectively negotiated prices.

Since its implementation in 2011, the German system of drug assessment and negotiation has achieved net prices [lower than those in the U.S.](#)⁶ The German system is among those [cited by the Trump administration](#)⁷ and by legislators from both the Democratic and Republican parties as a benchmark for rates that could be paid by Medicare. Yet the prices are high enough to attract manufacturers interested in launching drugs into the German market.

In the U.S., private payers extract price concessions from manufacturers by threatening to restrict physicians' prescribing (by requiring prior authorization and step therapy) and patient adoption (by imposing coinsurance and deductibles). The German system does not rely on these tools. The G-BA provides guidance to physicians on high-cost new medicines that includes the scope of the EMA market authorization, the G-BA's assessment of patient-relevant clinical benefits, safety precautions for use, and the price of the drug compared to those for available alternatives.

Physicians are free to prescribe any EMA-authorized drug that has been assessed by the G-BA without receiving prior approval from their patients' health plans. Regional physician associations develop percentage targets for prescription of generic over branded drugs and for biosimilars over branded biologics, with the goal of reducing expenditures. Consumer cost sharing is capped at a very modest 10 euros per prescription, with caps on out-of-pocket cost sharing for low-income patients and those living with multiple chronic conditions.

The carrots for manufacturers

The German pharmaceutical market has several features that are quite attractive to drug firms and keeps them interested in ensuring a long-term presence in Germany.

By statute, all drugs are covered and available for physician prescription in Germany immediately upon receiving market authorization by the EMA. In a drug's first year on the market, it is available at a price unilaterally determined by the manufacturer. During that year, the G-BA conducts comparative assessments and the sickness fund association negotiates prices, which are applied in the second and following years.

Once the insurer association has negotiated a price, it cannot interfere with physician prescription through prior authorization or with patient access by imposing additional cost sharing.

Pharmaceutical manufacturers can count on the actual volume of sales approximating pre-launch estimates that derive from demographic and epidemiologic factors. This contrasts with the frequent sales shortfalls experienced in the United States due to prior authorization and cost sharing.

The sticks for manufacturers

From the manufacturer's perspective, access to the German market is an all-or-nothing case. Failure to reach agreement with the insurer association reduces revenues to zero. In the U.S., by contrast, failure to reach agreement with one payer does not preclude agreement with others, and manufacturers will extract the highest prices from their least sophisticated negotiating adversaries.

Drug price negotiations in Germany function as a repeated game, since each manufacturer can expect to negotiate with the same purchaser for multiple products. Even small single-product pharmaceutical firms typically have signed co-marketing agreements with, and have their prices negotiated by, large multi-product manufacturers with a substantial presence on the German market. A manufacturer's reputation for reasonable pricing on one product will carry over to subsequent negotiations under the watchful eye of the sickness funds, the physician associations, patient advocacy organizations, and the Ministry of Health.

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The negotiation process is highly structured, with a statutory right to four confidential sessions and a constrained opportunity for extension to a fifth. Failure to agree during those sessions results in the drug being referred to an independent arbitration board. This board conducts its own assessment and does not merely split the difference between the insurers' and manufacturer's final price offers. The board does not negotiate, but unilaterally decides on a price it feels best accords with the drug's clinical value and society's need for cost control. From the establishment of the collective price negotiations structure from 2011 through March 2019, 230 drugs have gone through comparative benefit assessment and 35 of these have had their [final price decided by arbitration](#) ¹² rather than negotiation.

Manufacturers of drugs assessed by the G-BA as offering no incremental benefit must negotiate a price with the insurer association under a ceiling set by the price of the comparator therapy.

From 2011 to the end of 2018, the G-BA decided that [43% of new drugs](#) ¹² offered no incremental benefit, 18% offered positive but "non-quantifiable" benefits (mainly orphan drugs without comparator arms in their clinical trials), 17% offered only a

minor incremental benefit, 23% offered a moderate benefit, and just 1% offered a major benefit.

Conclusion

The German health care system achieves price moderation without the formulary exclusions, prior authorization requirements, and consumer cost sharing used by insurers in the United States. Its structure and processes offer potentially significant insights for drug policy discussions, and for Medicare price negotiations, in the United States.

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