

Clinical Assessment and Price Determination in the German Pharmaceutical System

James C. Robinson
Leonard D. Schaeffer Professor of Health Economics
University of California

The German System Shares Important Features with the US



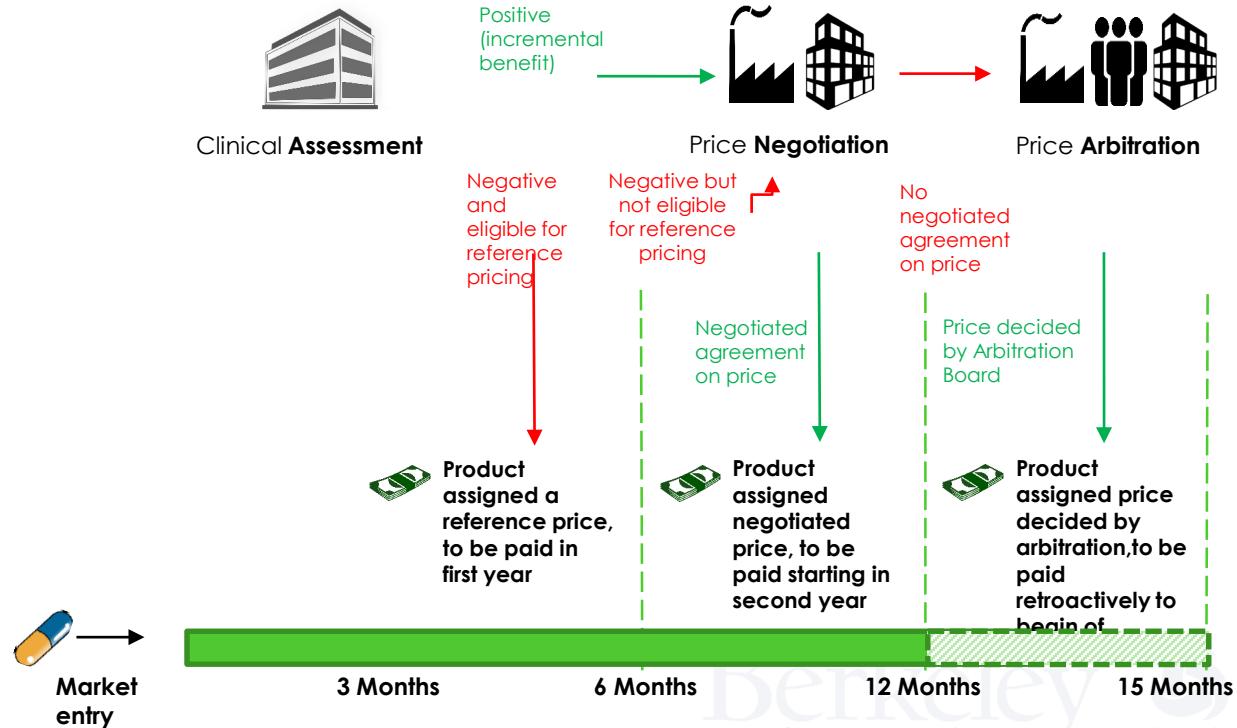
Germany at a Glance

Population = 82 million
Regionalized = 16 states
Rank of economy = #1 Europe

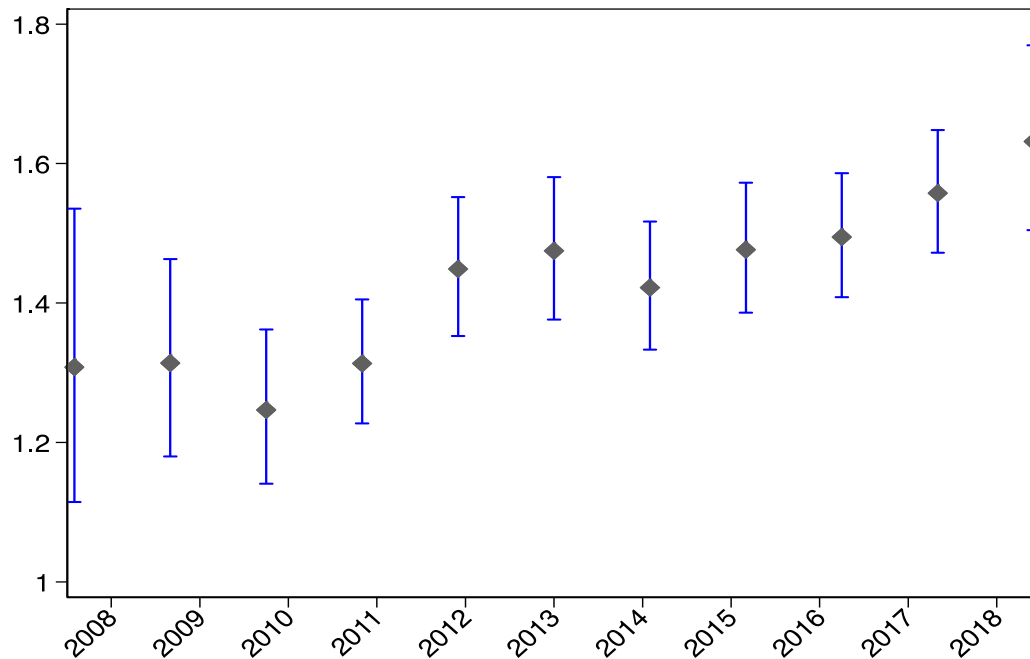
No public insurer
150 competing private insurers

Culture of patient access
Insurers must cover all drugs
approved by EMA (FDA)
Insurers cannot impose prior
authorization on physicians
Insurers cannot impose high
cost sharing on patients

Summary of the German Process



Lower Prices: Ratio of US/DE Net Prices for 80 Physician-Administered Drugs, 2008-18



US data from CMS Part B (ASP); DE data from LauerTaxe.

Structure and Process of Comparative Clinical Assessment



The Legitimacy of Benefit Assessment

- Clinical benefit assessment is difficult due to the multi-dimensional, rapidly changing, and always incomplete scientific evidence and patient values
- It is further complicated by being associated with policies on insurance coverage, pricing, and utilization management, which arouse fears in manufacturers, physicians, and patients
- The GBA process seems to have achieved (perhaps grudging) acceptance as evidence-based and patient-centric, rather than merely as a tool to help GKV-SV negotiate low prices
- This is a difficult feat, not to be taken for granted
- Which factors support social legitimacy?

Success Factors in Benefit Assessment: Structure

- Highly formalized process for each new assessment, with reliance on IQWiG (which is not cost-focused) as well as GBA internal staff
- Transparency of IQWiG methods, GBA hearings, documents, final assessments
- Repeated game: participants gain mutual familiarity (and trust?) across multiple drug assessments
- Implicit oversight by the Ministry of Health, to retain connection to political perspectives and imperatives, and to balance the legitimacy of GBA as self-governing body with the legitimacy of government as democratically elected body

Success Factors in Benefit Assessment: Participation

- Participation by manufacturers through early consultations, dossier preparation, public hearings
- Participation by patient advocates and organizations, with insights into patient experience of disease and treatment
- Participation by physician associations, to ensure GBA does not abrogate professional authority over treatment for individual patients
- Participation by Sickness Funds, with insights into patterns of utilization and spending among their enrollees

Structure and Process of Price Determination



The German Price Surprise

- Net prices in DE are lower than in the US
- This is surprising, since the DE culture and drug coverage structure would seem to limit leverage available to GKV-SV
 - Drugs are available for prescription immediately after EMA authorization
 - Insurers are not permitted to demand prior authorization and impose only weak retrospective audits on physicians
 - There is very limited cost sharing, not linked to drug price
 - Insurers must pay the price determined by negotiations or arbitration (no positive list)
- How does the DE achieve price moderation? Why do not manufacturers insist on receiving their full list prices?

Incentives for Agreement

- Some features of the DE system make its market and prices attractive to manufacturers, so that they have a strong desire to come to agreement even where their leverage is strong
 - A large drug market, prosperous economy, governmental budget surpluses, tight labor market, high visibility
 - Immediate reimbursement after EMA authorization, allowing drugs to gain physician and patient acceptance
 - Free pricing in first year, allowing for high short-term revenues and creating an anchor for subsequent rebate negotiations in DE and reference pricing in other nations
- Even if net prices are below what manufacturers would prefer, they are high enough to contribute positive contribution margins and help support R&D

Dis-Incentives for Dis-Agreement

- Mandatory arbitration increases uncertainty and risk. Board does not 'split the difference' between final payer and manufacturer offers, but conducts own assessment
- Repeated game: Aggressive price demands for drugs without substitutes could lead to aggressive payer demands for rebates for drugs with substitutes
- Reputational concerns: Pharmaceutical firms must accept the principle of efficiency (Wirtschaftlichkeit) underpinning the entire DE system, and fear political and public relations consequences of being viewed as undermining this
- If the AMNOG process is viewed as failing to deliver price moderation, and if the German economy were to enter a difficult period, there could be pressure for direct ceilings on drug prices, based on formal cost-effectiveness analysis (CEA) and budget impact analysis (BIA)

Further Reading

STAT, June 27, 2019

Negotiating drug prices without restricting patient access: lessons from Germany

By James C. Robinson, Dimitra Panteli, *and* Patricia Ex

June 27, 2019



Comparison with and Implications for the US Pharmaceutical System



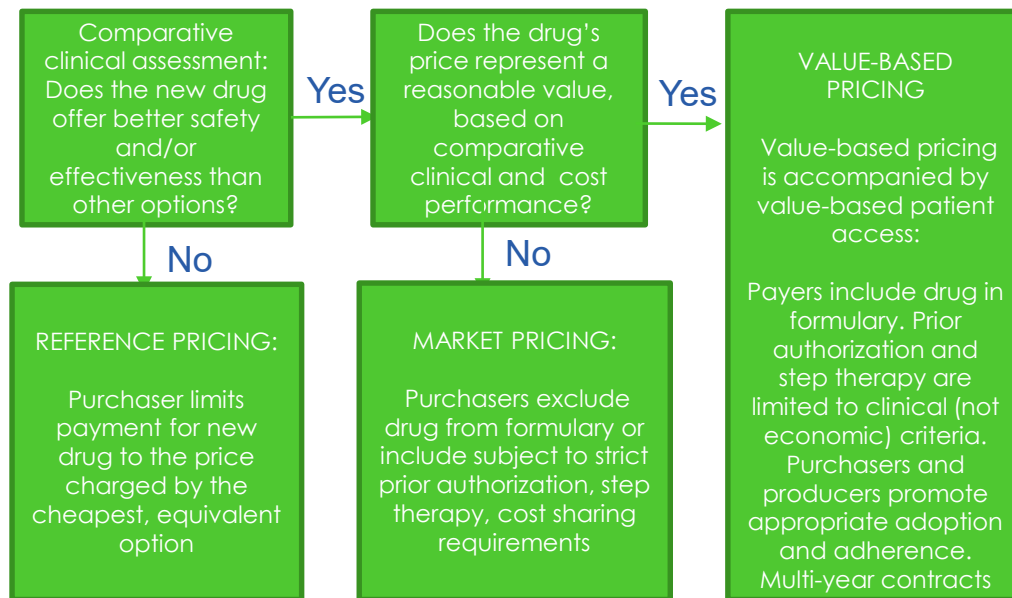
Comparative Clinical Assessment: Contrast with the United States

- In the US, HTA has been demonized by pharmaceutical firms, (some) patient advocacy organizations, and (many) politicians as a violation of individual patients rights and an obstacle to innovation
 - Governmental HTA bodies have been attacked, weakened, or dismantled altogether
- This leaves to the assessment task to each individual payer
 - Each payer must decide which drugs to include or exclude from coverage, and when to require prior authorization and step therapy from physicians
 - Physicians must comply with different coverage and utilization restrictions from each payer
- This de-centralized process further undermines the legitimacy of HTA, without offering a solution

Price Determination through Negotiation: Contrast with the United States

- The 'innovation race' has brought multiple therapeutically similar products to many specialty indications in the US, allowing payers to threaten patient access restrictions for drugs not offering a large (non-transparent) rebate
- To obtain rebates, payers have imposed formulary exclusions, physician prior authorization, patient cost sharing
- These tools have led to substantial reductions in physician prescription and patient access
- This has also generated significant price rebates, reducing margins for manufacturers

An Emerging Logic of Value-Based Pricing and Patient Access



Further Reading

JAMA, June 5, 2018

VIEWPOINT

Value-Based Pricing and Patient Access for Specialty Drugs

James C. Robinson, PhD, MPH
University of California,
Berkeley.

Scott Howell, MD, MBA
Novartis
Pharmaceuticals Corp,
East Hanover,
New Jersey.

Steven D. Pearson, MD, MSc
Institute for Clinical and
Economic Review,
Boston, Massachusetts.

Insurers, employers, and pharmacy benefit managers (PBMs) bemoan high prices for specialty drugs and respond by closely managing patient access to drugs through prior authorization, step therapy, and consumer cost sharing. Pharmaceutical firms are concerned when the use and sale of specific drugs fall short of projections. High prices and access barriers compound each other. Pharmaceutical firms help physicians to navigate utilization management and patients to cover their financial obligations, but then must consider the costs of these programs in subsequent prices. Payers respond to price increases by intensifying access management. Physicians and patients are caught between payers and manufacturers, facing ever-higher administrative and financial obstacles.

The list prices charged for specialty drugs have been rising rapidly in the past decade, both at the time of initial market launch and through post-launch increases.¹ Between 2005 and 2013, for example, the launch price of new oncology drugs increased 12% per year without commensurate increases in efficacy, implying that the price per life-year gained increased from \$139 000 to

been interrupted. When poorly designed and implemented, step therapy programs may also make it difficult for physicians and patients to avoid having to start again with therapies that patients have already “tried and failed” before (eg, when enrolled in a different health plan). Some health insurance plans feature annual deductibles and percentage co-insurance instead of dollar co-payments. These have created meaningful financial barriers to specialty drug access. In 2016, 23% of individuals with employment-based insurance had an annual deductible of \$2000 or more⁵ and 48% of Medicare Part D enrollees were subject to percentage co-insurance for specialty drugs.⁶

The concerns of insurers, manufacturers, physicians, and patients highlight the failure of the current model of drug pricing and access in the United States. Innovative purchasers and manufacturers are potentially interested in closer and longer-term relationships that support the need of the purchasers for affordability and the need of the manufacturers for patient access and net revenue. This requires a new framework for linking price negotiations with improved patient access.



The Berkeley Center for Health Technology (BCHT) promotes the efficiency and effectiveness of health care through research and education on the development, insurance coverage, payment, and appropriate use of medical technologies.

BCHT.Berkeley.Edu

