

Establish and communicate your healthcare product's value

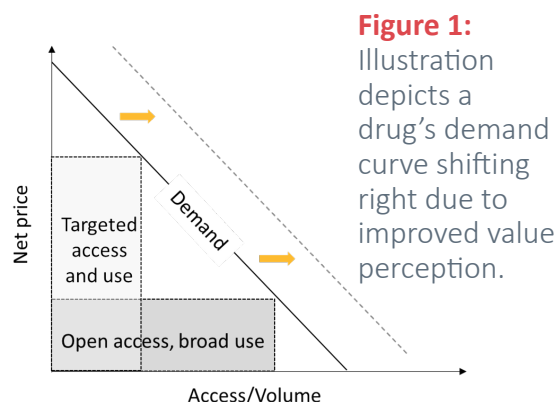
An exponential rate of innovation, increased competition, and the growth of cost containment pressures create a greater need to credibly establish the value of drugs and devices.

Shift the curve!

Global and U.S. market access teams partner with Certara to optimize product value, positioning, and evidence synthesis across all stages of the reimbursement journey.

Communicate meaningful product value to payers and achieve optimal market access

Our integrated approach supports early and near-launch pipeline assets and current portfolio products across all stages of development.



CONCEPTION

- Value Message Development
- Strategic market Access Plan
- Evidence Development Strategy
- Scientific Engagement
- Price and Payer Research
- Innovative Pricing and Contracting
- Economic Modeling and Advanced Analytics
- Profile Testing, Positioning
- Real World Impact Modeling

- Database Studies, Chart Reviews and Surveys
- Consistency and Continuity: Comprehensive Lifecycle Support

- Systematic Literature Review and Evidence Synthesis
- Communications (Manuscripts, Presentations, Workshops, Trainings, Mock Negotiation)

SUBMISSION

- Value Demonstration, Dossiers and HTA Strategy
- Global Reimbursement Submissions

Case Study: RWE study cited in NIH Covid-19 treatment guidelines

Situation

Client needed to generate high-quality, real-world evidence to support the use of remdesivir and inform the scientific community as it relates to treatment recommendations for patients hospitalized with Covid-19. Significant urgency and a lack of existing clinical trial data made this mission even more challenging.

Solution

As part of an ongoing collaboration that began in December 2020, Certara designed and implemented a real-world study comparing the effectiveness of remdesivir vs. standard-of-care at reducing Covid-19 mortality using one of the largest, geographically representative hospital discharge databases in the US.

Results

The collaboration had a significant and immediate impact on treatment guidelines and has been widely cited by the scientific community. The body of evidence supporting remdesivir has been cited in seven peer-reviewed publications to date, and real-world evidence (RWE) generated during as part of the collaboration was cited in NIH Covid-19 treatment guidelines.¹

Optimizing the clinical and economic value of your innovations

Advanced analytics, modeling, and longstanding relationships in the payer and health technology assessment (HTA) communities help market access teams make better informed decisions and clearly demonstrate value.

Assessing value

- Market access landscapes / analog research
- Forecast development
- Evidence-based financial model inputs
- Integrated stakeholder pricing models
- Commercial due diligence

Improving value

- HEOR modeling and analysis
- Real world evidence (RWE) design and execution
- Systematic Literature Reviews (SLRs)
- Clinical and payer endpoint optimization
- Trail design validation with payers and KOLs

Identifying and actioning differential value

- Indication / product sequencing
- Country launch sequencing
- Pricing and contracting strategy
- In-market price optimization
- Payer segmentation
- Channel segmentation

Communicating value

- Value message development, testing and communication
- Payer-facing materials and tools
- GVD/AMCP dossiers, value decks
- BaseCase value communication platform

I was very impressed by the methodology Certara uses to develop a price recommendation

- CEO, Global biotech company focused on innovative medicines to treat neurological diseases

CERTARA[®] OUR NETWORK

Proprietary panel of vetted payers and decision makers

- National accounts (including 7 of the top 10 plans and PBMs)
- Dominant regional health plans
- Hospital P&T committee members
- Employee benefits consultants
- GPOs and specialty pharmacies
- LTC chain pharmacies
- Risk-based physician practices



200+ current and former payers & HTAs

- HTA members: HAS (France), GBA (Germany), AIFA (Italy), NICE (UK)
- National pricing commissions: CEPS (France), Association of Sick Funds (Germany), Health Ministry (Spain, Netherlands), AIFA (Italy)
- Regional payers
- Local payers / hospital P&T members



Case study: Interactive hospital stakeholder application changes minds, opens doors

Situation

Device manufacturer must overcome financial objections from potential hospital customers.

Solution

- Certara designed an interactive software application populated with RWD comparing the customer institution to the national average.
- Contains a tool allowing customer input, demonstrating that the additional reimbursement resulting from device use would pay for the device and increase hospital margin contribution.

Results

The application is well received by the customer's account team; data is refreshed annually, and the application remains in use today.

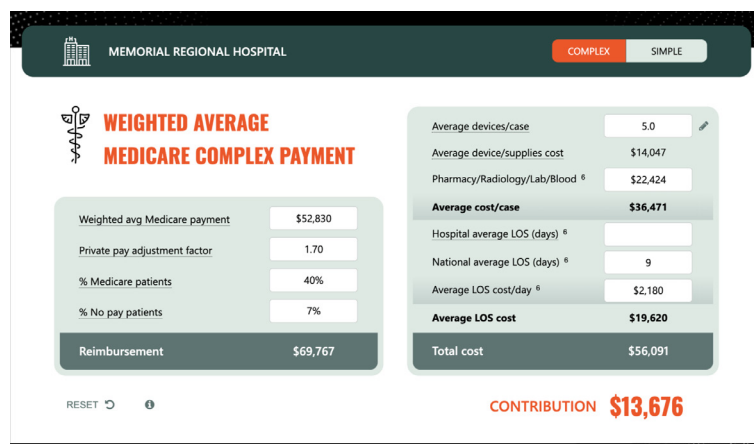


Figure 2: An interactive application built on the BaseCase communication platform allows user input to estimate reimbursement.

Case study: Patient voice shifts internal product perception

Situation

- Client wanted to make a go/no-go decision to continue development of an implantable device for their drug.
- Internal perception of the product was low, as a similar product was withdrawn from the market and a long-acting version of the drug had recently launched.

Solution

Certara conducted interviews with current patients and identified a very strong interest in the device, given the brand equity of the drug and the potential for significant improvement in quality of life.

Results

- Project changed leadership attitudes toward the product.
- Client decided to continue development of device.

Case study: Channel pricing modeling shapes clinical development plan

Situation

Client was deciding whether to formulate an in-development drug as an IV or an injectable.

Solution

Certara modeled the pricing potential for the IV and the subcutaneous formulations, considering:

- WAC/year
 - Anticipated payer mix
 - Distribution costs
 - Wholesaler discounts
 - GPO fees
- Part D discount program
 - Medicaid Drug Rebate Program
 - Cost-share support program
 - 340B pricing
 - FFS discounts

Results

- Analysis demonstrated that the gross-to-net (GTN) estimate was more favorable for the IV formulation, given Part D and 340B deductions.
- Model can be updated if client’s internal assumptions change in the future.

Weighted average discount

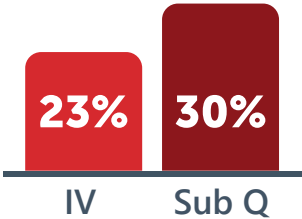


Figure 3: A graph comparing the weighted average discount shows a more favorable GTN estimate for the IV formulation.

Case study: Optimizing price across multiple sites of care

Situation

Client was launching a product that is initiated as an IV in the inpatient setting and continued as an oral when the patient is discharged.

Solution

Certara mapped the impact on treatment choice and willingness-to-pay of stakeholders across the sites of care, for both formulations.

Results

Research identified differences in decision-making and price sensitivity informed pricing recommendations.

	IV	Oral
Setting	Inpatient	Outpatient
Key decision-makers	P&T committee, Infectious Disease dept	MCO payers
Willingness to pay	Lower, more variation	Higher, less variation
Guiding philosophy	Right drug for right patient	Ensure continuity from inpatient, prevent readmissions
Recommended pricing strategy	WAC: Lower Contracts: Selective, to access priority hospital formularies	WAC: Higher Contracts: minimal

Table 1: Product comparison and strategies for different routes of administration and sites of care.

Case study: pricing for a novel product

Situation

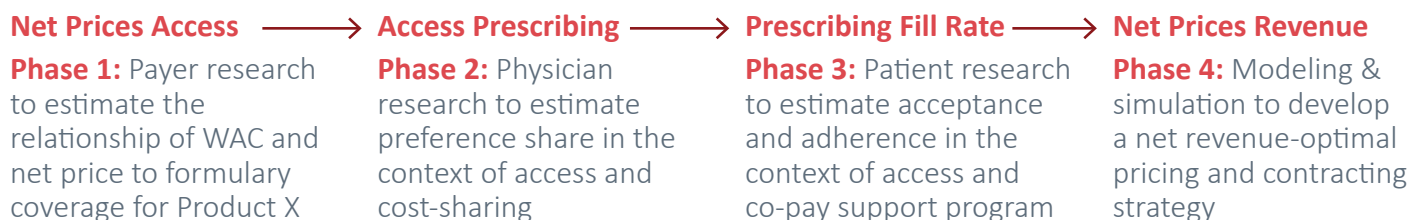
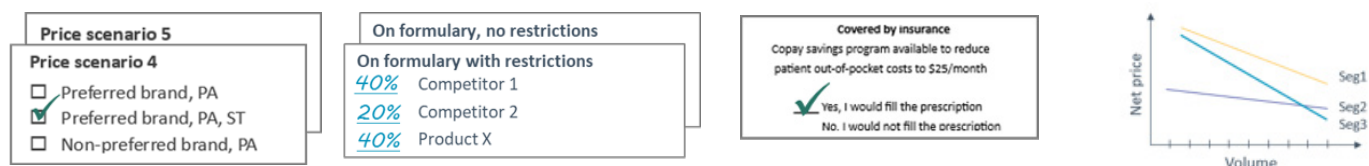
Client was launching a novel product in a class with high out-of-pocket costs.

Solution

Certara modeled the impact of WAC, contracting and copay support across payers, prescribers and patients.

Results

Model was well-received and client intends to follow pricing recommendation.



References

¹ NIH Covid-19 Treatment Guidelines – Therapeutic Management of Hospitalized Adults with Covid-19; <https://www.covid19treatmentguidelines.nih.gov/management/clinical-management-of-adults/hospitalized-adults--therapeutic-management/>



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At Certara, we accelerate medicines to patients, partnering with life science innovators. Together we advance modern drug development with biosimulation, regulatory science, and market access solutions.
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