PRMA Insights:
Pricing and Reimbursement Success in COPD

PRMA Insights provide in-depth understanding of current and future market access realities, developed by industry-experienced experts with comprehensive cross-functional knowledge. Critical insight into the clinical and payor landscape is supported by actionable strategic insights, providing a cornerstone on which to build a successful market access strategy.

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Pricing and reimbursement success

Achieving market success is becoming ever more challenging as payors seek to rationalize restricted budgets on increasingly numerous – and frequently expensive – products. Success requires a thorough understanding of the current P&R landscape, and how it is changing, and careful, strategic planning – from as early as Phase 2.

PRMA Insights are a key resource that provides the basis for your planning. We have analyzed the current treatment landscape in detail, and have identified the key issues that need to be addressed in developing the market access strategy.

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Introduction

COPD offers an attractive commercial opportunity provided that key market access challenges can be overcome. Payors are willing to provide access to medicines for COPD, but the evidence requirements for achieving reimbursement and broad market access are increasingly demanding, and vary between major markets.

A robust market access strategy is key to commercial success

Prescription drugs developed for respiratory indications have generally enjoyed commercial success. However, new products will face significantly greater challenges in achieving similar success, as the patents of leading products expire and increasingly stringent cost-containment measures are imposed by governments. Payors will be asking increasingly challenging questions about relevant outcomes, trial durations, and active comparators. A novel mechanism of action and a more convenient administration form will not be enough to achieve optimum market access and premium price if they are not supported by robust clinical, safety, and economic data derived from studies that are designed to meet payors’ expectations. Data demonstrating incremental therapeutic benefit (and long-term benefits) versus relevant comparators will also be crucial. For example, the first selective phosphodiesterase inhibitor to be launched in the EU offered a new therapeutic class and an oral once-daily option for add-on therapy in patients with severe COPD. However, in early HTAs payors criticized the comparator used in trials and clinical data relating to exacerbation rates used in the economic analysis.

European payors have provided comprehensive commentary on the design of clinical studies in COPD, criticizing the lack of explicit operational definitions of stable COPD, disease severity, and exacerbations; the outcome measures selected (these should go beyond FEV1); the inadequate powering of secondary outcomes; the use of concomitant medication that is not in line with available treatment guidelines; and the too-short duration of clinical studies and economic models. Manufacturers need to take such criticisms into account when designing Phase 2 and 3 trials. In particular, eligibility criteria in terms of reversibility of airway obstruction need to be clearly defined, so that COPD is clearly distinguished from asthma; payors’ expectations in terms of scales to define disease severity and FEV1 cut-off points also need to be considered.

There is clearly a need for new products that can be used at an early stage of COPD to delay – and ideally prevent – disease progression, improve survival, and reduce future complications, thereby leading to tremendous cost savings. Beyond the absence of curative therapy, current treatment options have other inherent limitations, such as tolerability profiles, which also compromise adherence to treatment. Although much of the trial activity relates line extensions, six investigational compounds are being assessed in 28 Phase 3 trials. The maximum duration of the ongoing studies is 52 weeks and the majority focus on improvement in FEV1, reduction in exacerbations, safety, and HRQoL, primarily compared with placebo.

Treatments that target airway inflammation may be more likely to improve lung function and decrease the frequency and severity of exacerbations – a key cost driver in COPD. Such treatments could be claimed as innovative and potentially attract a premium price. However, longer trials will be needed to demonstrate these benefits.

Generating an evidence package that is consistent with pricing and commercial ambitions requires early planning (Phase 2 or earlier) and broad cross-functional cooperation. Failure to adequately plan and invest in the market access strategy could lead to commercially disastrous consequences such as lower achievable price, smaller-than-planned reimbursed population, and extensive market access delays.

A backdrop of global P&R reform

In planning a successful market access strategy, manufacturers need to understand and accommodate the reforms that are influencing regulatory requirements, HTA, and P&R across many of the major markets. This PRMA Insights strategic resource considers such issues, and highlights those that are likely to affect strategy development.

PRMA Insights: The Roadmap to Pricing and Reimbursement Success in COPD unravels the complexity around P&R in this market and delivers actionable strategic insights to apply to your global product development program, in order to ensure that you develop a robust evidence-based payor value proposition and achieve commercial success.
6 steps for pricing and reimbursement success

1. Understanding the current treatment landscape
   - Reviews of international, national, and local clinical guidelines
   - Changing approaches and attitudes to treatment
   - Regulatory indications for the scope products
   - Pivotal trial data for the scope products and overview of key elements of clinical trial design, such as subpopulations, comparators, and endpoints
   - Future treatment landscape – products in Phase 3 and the likely challenges these products will face

2. Understanding the HTA and P&R environment
   - Overview of the current P&R process in the scope countries (US, EU major 5, and Japan)
   - Focus on areas that are changing and how this could affect strategy development

3. Comprehensive review and analysis of relevant HTAs and P&R decisions
   - Critical analysis of reviews and decisions made by:
     > NICE > SMC > AWMSG > CEPS
     > TC > IQWIG > G-BA > DGFFP
     > CIPM > GENESIS > AIFA > MHLW
     > regional and hospital evaluations in Spain and Italy
   - The value propositions and arguments that manufacturers submitted
   - What worked – and what didn’t
   - Payors’ criticisms and expectations
   - Ways to achieve differentiation

4. Disease burden
   - Epidemiology of the disease and relevant subpopulations
   - Analysis of cost burden and presentation of relevant key data
   - Measurement of utilities
   - Critique of cost-effectiveness analysis and budget impact models
   - Payors’ expectations relating to cost arguments, and how these are changing

5. Understanding the role of PROs
   - PROs as a potential differentiating factor
   - What needs to be measured
   - Suitable instruments
   - Expectations of the regulatory and HTA agencies
   - Strategies for inclusion of PRO claims on the product label

6. Designing the clinical development program to support market access
   - Expectations of regulatory bodies and payors
   - Choice of comparators in clinical trials to meet payors’ expectations
   - Appropriate endpoints
   - Importance of patient subpopulations and how these should be defined
   - Measurement of PROs – relevant tools and instruments

PRMA Strategic Insight
Developed by our in-house experts, PRMA Strategic Insights provide critical advice to manufacturers in planning their market access strategy. They are listed together in each Chapter Summary and in the Executive Summary, as well as being located at relevant points in the text.
Author profiles

PRMA Insights are developed by consultants with wide-ranging experience of all aspects of market access, pricing, and reimbursement and are validated by national and international opinion leaders.

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David is the founding partner of PRMA Consulting. He has more than 15 years’ experience in P&R, market access, and health outcomes and has held senior leadership roles at Lilly and J&J. David has developed European and global P&R and market access programs to quantify, capture, and communicate product value, including several products launched across multiple therapy areas. David has published extensively in the area of health economics.

**Sotiria Papanicolaou**
Sotiria has more than 10 years’ experience in the pharmaceutical industry. She has worked in the corporate leadership team of Janssen-Cilag, Greece, and in a number of EMA and global strategic market access teams. Sotiria was also part of the European Health Outcomes Research group at Lilly, where she developed health economics and outcomes strategies to support local P&R negotiations for new products.

**Dr Mark Larkin**
Mark has over 10 years’ experience in strategy consulting and finance. He has been involved in strategy development across a broad range of therapeutic areas, at both European and global levels, and has extensive experience of advising North American and European developers on P&R and market access strategies, for both in-house launches and to support business development objectives.

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Clare has over 12 years’ experience working in R&D and marketing within biotechnology and medical devices. Clare has been responsible for aspects of strategy and marketing relating to development of novel radiopharmaceuticals, software for medical imaging and in vitro diagnostics, and pharmaceutical business development.

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**Dr Alicia Gil**
Alicia has more than 14 years’ experience in the pharmaceutical and biotechnology industry, and has been involved in the development and execution of regulatory affairs and market access strategies through all phases of drug development and commercialization, in a range of therapeutic areas. Alicia has an in-depth understanding of the Spanish healthcare system and market access challenges that it presents.

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Alberto has more than 25 years’ experience in the pharmaceutical industry. He has been an international manager in P&R and outcomes research, with broad experience in business planning, market research, and new product development at corporate level. Alberto has an in-depth understanding of the Italian healthcare system and market access challenges.

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Our in-house US expert, Vanessa has more than 10 years’ consultancy experience in healthcare and life sciences commercialization strategy, with a strong background in managed markets, including reimbursement dynamics among public and private payors in the US.

**Monika Behrens**
Monika has more than 15 years’ experience in the pharmaceutical industry and statutory health insurance. Before joining PRMA she was in charge of market access strategy for GlaxoSmithKline in Germany, the UK, and Europe for a broad range of therapy areas. Monika has an in-depth knowledge of the German healthcare system, particularly the AMNOG legislation.
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7.3 Expenditure control

Historically, manufacturers were free to set prices in the German market at will. Over the last decade, however, the G-BA has developed a broad range of criteria to restrict the number of drugs that are eligible for unconditional remuneration at the price set by the manufacturer, as described in Table 7.3 (previously).

7.4.1 Reference pricing and patent status

The reference price system, which is controlled by the G-BA, is a powerful instrument for cost containment. In 2007 it covered approximately 15% of prescriptions and of sales, and generated an estimated cost saving of €6.3 billion.

Reference groups are determined by the G-BA but the prices are set by the GKV-Spitzenverband (see Table 7.5). A product can be assigned to a reference price group on the basis of three different criteria:

- Level 1: Identical substances (i.e., generically equivalent).
- Level 2: Substances that are therapeutically similar with different therapeutic effects, especially chemically related ("near" pairs).
- Level 3: Substances that are therapeutically similar with no different therapeutic effects, especially chemically unrelated.

7.4.2 Reimbursement success in COPD

The approval status of COPD treatments is important for the granting of reimbursement. The reference is based on the outcomes of the clinical trials. The most important clinical endpoints are the efficacy, safety, and quality of life. The reimbursement process begins with the submission of the dossier to the IQWiG, which is an independent institute that assesses the cost-effectiveness of medical treatments. The dossier contains data from clinical trials, real-world evidence, and patient surveys.

7.4.3 Reference price system for COPD

The reference price system for COPD is a powerful instrument for cost containment. In 2007 it covered approximately 15% of prescriptions and of sales, and generated an estimated cost saving of €6.3 billion.

The reference price system is used to determine the cost of a new drug compared to existing therapies. The reference price is based on the price of a similar drug that is already reimbursed in Germany. The reference price is set by the GKV-Spitzenverband, which is an association of the sickness funds.

7.5.1 Reimbursement process

The reimbursement process for COPD treatments is a complex and lengthy process. It begins with the submission of the dossier to the IQWiG, which is an independent institute that assesses the cost-effectiveness of medical treatments. The dossier contains data from clinical trials, real-world evidence, and patient surveys.

The reimbursement process is divided into three stages:

1. Decisionalсоединенчиих (Innovative Class; for drugs perceived to provide no additional benefit)
2. Reference price setting (for drugs perceived to provide additional benefit, but not considered to be superior to the reference drug)
3. Materials and methods (for drugs perceived to provide additional benefit and considered to be superior to the reference drug)

7.6.1 Treatment of COPD

The treatment of COPD is based on a combination of pharmacological and non-pharmacological interventions. The main goals of treatment are to improve symptoms, reduce the frequency and severity of exacerbations, and improve quality of life.

7.6.1.1 Pharmacological treatment

The standard of care for COPD includes a combination of long-acting beta2-agonists and inhaled corticosteroids. These drugs help to reduce the symptoms of chronic bronchitis and improve lung function.

7.6.1.2 Non-pharmacological treatment

Non-pharmacological interventions for COPD include smoking cessation, exercise therapy, and pulmonary rehabilitation. These interventions help to improve physical fitness, reduce the risk of exacerbations, and improve quality of life.

7.6.2 Outcome measures

The primary outcome measures for COPD treatment include improvements in lung function, quality of life, and exacerbation rates. Secondary outcome measures include improvements in symptoms, functional status, and adherence to treatment.

8. Pricing and reimbursement in Spain

Spain has a centralized reimbursement system for new drugs. The pricing and reimbursement process is managed by the Spanish Ministry of Health through the National Institute of Health (INSCS). The INSCS evaluates the therapeutic value and cost-effectiveness of new drugs and sets the reimbursement price. The reimbursement price is based on the cost of production and includes a profit margin for the manufacturer.

8.1.1 Prescribing patterns

Prescribing patterns for COPD treatments in Spain are influenced by factors such as the cost of the drug, the reimbursement status, and the availability of generic alternatives.

8.1.2 Reimbursement success

Reimbursement success for COPD treatments is driven by factors such as the therapeutic value, cost-effectiveness, and market access.
## Ways to use PRMA Insights

PRMA Insights provide a key resource for development of your P&R and market access strategy. This diagram illustrates just a few of the many ways that this can support your planning.

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<th>Activity</th>
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| Development of an HEOR strategy and evidence-generation plan | All chapters | Understand:  
- Competitor data packages
- Adverse-effect profiles
- Indirect comparisons
- Existing utility estimates
- Registries in the scope countries (data captured and how these can be used)
- Supporting development of economic models
- Evidence gaps and future evidence generation |
| Development of a PRO strategy | Chapter 3 | Understand:  
- Role of PROs in product differentiation
- Impact of PROs on HTA and P&R submissions
- Existing PRO data for marketed products and label claims
- Evolution of a PRO strategy |
| Development of a preference-based utility strategy | Chapter 5, Chapter 7 (UK) | Understand:  
- Existing utility estimates in the literature and how these have been applied to cost-effectiveness models of competitor products
- Mapping to EQ-5D to generate utilities
- How such estimates map onto different symptoms that may be able to drive utility differences |
| Critical understanding of existing HE models | Chapter 5, Country-specific chapters (6–12; particularly 7 [UK]) | Understand:  
- Critically assess existing models, assumptions, and inputs (cost, utility, and clinical) |
| Competitor AE profiles | Chapter 4 and country-specific chapters | Understand:  
- Impact of AEs in economic models
- HTA feedback on relevant AEs to include in models |
| Inform clinical development program (endpoints, subgroups) Inform HTA strategy Inform cost-effectiveness model | All chapters | Understand:  
- Competitors’ HTA and clinical development strategies (existing products and products in development)
- Benefits according to different subgroups and definitions used in trials
- Feedback from payors and HTA agencies on submitted evidence and needs for future research |
| Develop and inform value propositions | Chapters 3–5, Country-specific chapters | • Understand the value propositions of competitors and their acceptance by payors  
- Provide the basis for the global value dossier of a new product |
| Internal education | All chapters | Use as educational materials to enable colleagues to rapidly become familiar with a new therapy area and the market challenges |
| Cross-functional collaboration | All chapters | Ensure common understanding across the organization in order to develop a single coherent strategy that meets various stakeholders’ needs in:  
- Market access challenges and opportunities
- HEOR strategy development
- Clinical development strategy
- Regulatory expectations in terms of indication, clinical trial design, and PROs
- Accurate forecasting of the market opportunity
- A consistent value proposition that supports both market access and marketing |
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