COPD Pricing, Reimbursement, and Access

Description: In-class competition and generic entry provide payers with leverage to demand favorable pricing for inhalers in exchange for formulary access.

This report addresses the following questions:

- Which LABA/LAMAs have been most successful in securing national reimbursement and why?
- How do US and European payers and physicians view the launch of once-daily Breo?
- What discounts and market access levers will be required to drive uptake of generic ICS/LABA inhalers?
- What impact will generic ICS/LABA inhalers have on pricing and reimbursement of triple combination ICS/LABA/LAMA therapies?
- What role will biologics play in the treatment of COPD?

Contents:

EXECUTIVE SUMMARY

MARKET CONTEXT

- While traditional first-line medications face generic competition, pipeline triple combinations and LABA/LAMAs will fuel modest growth in COPD
- Marketed COPD products in the US, Japan, and five major EU markets
- Pipeline COPD treatments in late-stage development
- Bibliography

GLOBAL PAYER AND KEY OPINION LEADER INSIGHTS

- Insights and strategic recommendations
- Physicians are looking forward to triple therapy combinations for severe COPD patients
- Payers are less impressed with triple therapy combinations, with potential for overprescribing a concern
- LABA/LAMAs set to overtake ICS/LABAs in non-exacerbating COPD patients
- Key opinion leaders believe IL-5 biologics are unlikely to play a major role in COPD
- Some payers welcome second-generation LAMAs, but they are unlikely to displace Spiriva as the market leader
- Unclear product differentiation among branded ICS/LABA products is driving price competition
- Reversal of disease progression is considered one of the main unmet needs in COPD
- Once-daily dosing matters less to physicians than having access to both once-daily and twice daily inhalers
- US and EU payers and physicians want more economically impactful, easily quantified outcomes,
- Longer clinical trials with clinically significant results favored by both US and EU payers
- Bibliography

US PRICING

- Pricing of LABA/LAMAs is comparable to ICS/LABAs
- Spiriva Respimat is priced at a discount over the HandiHaler device,
- Bibliography

US PAYER INSIGHTS

- Insights and strategic recommendations
- Co-pays continue to determine patients' therapeutic choices
- Payers will welcome generic ICS/LABA inhalers, but physicians are more sceptical
- Strong respiratory portfolio opens possibility for bundled contracting with some payers
- Bibliography

US REIMBURSEMENT
- Insights and strategic recommendations
- Trends in COPD drug expenditure
- GOLD guidelines are widely used for COPD
- Formulary tier positioning is the key utilization management tool used in COPD
- Generic Advair entry to the US market is a real threat for GlaxoSmithKline
- Bibliography

JAPAN

- Price premiums are awarded for added benefit or innovation
- Pricing of launched COPD treatments
- Pricing of LABA/LAMAs in Japan is considerably higher than ICS/LABAs
- Bibliography

FIVE MAJOR EU MARKETS PRICING

- First-to-market Utibron enjoys high prices in most EU markets

FIVE MAJOR EU MARKETS PAYER INSIGHTS

- Insights and strategic recommendations
- Inhaler spend is one of the top budget items for European payers with high visibility
- Access to COPD inhalers relatively unrestricted in the five major EU markets
- With the exception of the UK, GOLD remains the most frequently used guideline in EU Countries
- Bibliography

GENERIC ICS/LABA INHALERS IN THE FIVE MAJOR EU MARKETS

- Insights and strategic recommendations
- Generic versions of Advair and Symbicort struggle to gain market share
- Generic versions of Advair have received limited approval and continue to see low market penetration in the EU
- Generic Symbicort product DuoResp gains traction in the EU
- Generic tiotropium uptake highly dependent on determination of device substitutability for single inhaler LAMAs
- Bibliography

FRANCE

- Insights and strategic recommendations
- ASMR rating has an impact on pricing
- Head-to-head trials of LABA/LAMAs vs ICS/LABAs likely to trigger a review by the TC and permit further education efforts
- ICS/LABA/LAMA combinations unlikely to receive ASMR higher than V
- Branded generic versions of Advair and Symbicort have been reviewed by the TC
- Bibliography

GERMANY

- Insights and strategic recommendations
- Positive assessment from the G-BA will impact price negotiations
- Sickness funds tender for branded combination ICS/LABAs; uptake of generics remain low
- COPD medications are subject to indicative budget limits but relevance of this restriction may change under ongoing reform
- Bibliography

ITALY

- Insights and strategic recommendations
- AIFA is responsible for pricing and reimbursement decisions
- Delays in inclusion on regional formularies hamper access for recently launched inhalers
- Approvals of LABA/LAMAs Anoro and Utibron with treatment plan provision will further restrict market
uptake
- AIFA register is an access obstacle for Daliresp; prescription volumes remain low
- In the absence of restrictions from AIFA and regional decision-makers, the choice between branded vs generic combination inhaler is left to the physician
- Bibliography

SPAIN

- Insights and strategic recommendations
- National reimbursement decisions are not a barrier to access
- Some general physicians are subjected to prescribing limitations for COPD drugs
- None of the COPD drugs evaluated in IPTs offer additional therapeutic benefit
- Regional assessments are an additional market access step
- Bibliography

UK

- Insights and strategic recommendations
- NICE approval is a key access barrier in the UK
- Daliresp is restricted to patients with COPD currently undergoing clinical trials
- NICE recommends most economical option for LABA/LAMA combinations; choice down to regional commissioners
- NICE COPD treatment guidelines are used by NHS physicians
- SMC decisions
- Bibliography

METHODOLOGY

- Price assumptions
- Exchange rates
- Bibliography

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