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

Ordering:
Order Online - http://www.researchandmarkets.com/reports/3797407/
Order by Fax - using the form below
Order by Post - print the order form below and send to

Research and Markets,
Guinness Centre,
Taylors Lane,
Dublin 8,
Ireland.
Fax Order Form
To place an order via fax simply print this form, fill in the information below and fax the completed form to 646-607-1907 (from USA) or +353-1-481-1716 (from Rest of World). If you have any questions please visit http://www.researchandmarkets.com/contact/

Order Information
Please verify that the product information is correct and select the format(s) you require.

- **Product Name:** Copd Pricing, Reimbursement, and Access
- **Web Address:** http://www.researchandmarkets.com/reports/3797407/
- **Office Code:** SC

Product Formats
Please select the product formats and quantity you require:

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Electronic (PDF) - Single User:</th>
<th>USD 7500</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Electronic (PDF) - Enterprisewide:</td>
<td>USD 26250</td>
</tr>
</tbody>
</table>

* The price quoted above is only valid for 30 days. Please submit your order within that time frame to avail of this price as all prices are subject to change.

Contact Information
Please enter all the information below in **BLOCK CAPITALS**

- **Title:**
  - [ ] Mr
  - [ ] Mrs
  - [ ] Dr
  - [ ] Miss
  - [ ] Ms
  - [ ] Prof

- **First Name:** [ ]
- **Last Name:** [ ]
- **Email Address:** *
- **Job Title:** [ ]
- **Organisation:** [ ]
- **Address:** [ ]
- **City:** [ ]
- **Postal / Zip Code:** [ ]
- **Country:** [ ]
- **Phone Number:** [ ]
- **Fax Number:** [ ]

* Please refrain from using free email accounts when ordering (e.g. Yahoo, Hotmail, AOL)
Payment Information

Please indicate the payment method you would like to use by selecting the appropriate box.

☐ Pay by credit card: You will receive an email with a link to a secure webpage to enter your credit card details.

☐ Pay by check: Please post the check, accompanied by this form, to:

Research and Markets,
Guinness Center,
Taylors Lane,
Dublin 8,
Ireland.

☐ Pay by wire transfer: Please transfer funds to:

Account number 833 130 83
Sort code 98-53-30
Swift code ULSBIE2D
IBAN number IE78ULSB98533083313083
Bank Address Ulster Bank,
27-35 Main Street,
Blackrock,
Co. Dublin,
Ireland.

If you have a Marketing Code please enter it below:

Marketing Code: 

Please note that by ordering from Research and Markets you are agreeing to our Terms and Conditions at http://www.researchandmarkets.com/info/terms.asp

Please fax this form to:
(646) 607-1907 or (646) 964-6609 - From USA
+353-1-481-1716 or +353-1-653-1571 - From Rest of World