Psoriatic Arthritis Pricing, Reimbursement, and Access

Description: An absence of head-to-head trials, along with biosimilar launches, provide payers with leverage to demand favorable pricing for branded products in exchange for formulary access.

This report addresses the following questions:

- What access controls are payers imposing on interleukins in psoriatic arthritis?
- What discounts and market access levers will be required to drive uptake of interleukins and second-generation TNFalpha inhibitors?
- How do US and European payers view the launch of oral small molecules in psoriatic arthritis?
- What impact will biosimilar entry have on pricing and reimbursement of branded biologics?

Contents:

EXECUTIVE SUMMARY

MARKET CONTEXT

- Market growth due to price increases and rising prevalence will be offset by biosimilar entry
- Marketed psoriatic arthritis products in the US, Japan, and five major EU markets
- Pipeline psoriatic arthritis treatments in late-stage development
- Bibliography

GLOBAL PAYER INSIGHTS

- Insights and strategic recommendations
- Spend on psoriasis and psoriatic arthritis drugs is moderate, but may vary depending on the patient population
- Recently launched agents struggle to compete with TNF-alpha inhibitors
- Dosing frequency and route of administration act as differentiating factors for TNF-alpha inhibitors
- US and EU payers and physicians want head-to-head trials to assess efficacy directly and determine pricing,
- Longer clinical trials with statistically and clinically significant results are favored by both US and EU payers
- The psoriatic arthritis pipeline suffers from a dearth of promising candidates
- Varying dosing and method of administration are important for patients, but oral formulation does not warrant a higher price
- Bibliography

US PRICING

US PAYER INSIGHTS

- Insights and strategic recommendations
- Drugs with approvals in multiple inflammatory indications are favored in payer contracting
- Psoriasis is usually approved first, but expanding to psoriatic arthritis is beneficial for pipeline and marketed drugs
- Inflectra, the first TNF-alpha biosimilar, is approved by the FDA, but launch could take years due to legal battles
- Bibliography

US REIMBURSEMENT

- Insights and strategic recommendations
- Trends in psoriatic arthritis drug expenditure
- Bibliography

JAPAN

- Price premiums are awarded for added benefit or innovation
FIVE MAJOR EU MARKETS PRICING

FIVE MAJOR EU MARKETS PAYER INSIGHTS

- Insights and strategic recommendations
- Access to biologics is mostly restricted in the five major EU markets, with a variety of tools used to curb access

BIOSIMILAR TNF-ALPHA INHIBITORS IN THE FIVE MAJOR EU MARKETS

- Insights and strategic recommendations
- Uptake of biosimilar TNF-alpha inhibitors varies across UK markets as the EMA does not determine interchangeability
- Most physicians and payers consider biosimilars to be interchangeable, and an opportunity to reduce costs, but worries around indication extrapolation remain
- Payers use biosimilars to pressure originators on pricing
- Hospitals continue to procure both biosimilars and originators; dynamic pricing environment observed
- Biosimilars will be used as price benchmarks for pipeline agents
- Payers are unlikely to implement strong incentives to drive uptake of biosimilar infliximab due to limited use of the drug
- Bibliography

FRANCE

- Insights and strategic recommendations
- ASMR rating has an impact on pricing
- Access restrictions for biologics are minimal, and are largely determined by national Transparency Committee guidelines
- Both IL-
- Cosentyx and Taltz are likely to get ASMR V from the TC
- Bibliography

GERMANY

- Insights and strategic recommendations
- Positive assessment from the G-BA will impact price negotiations
- Certain sickness funds subject TNF-alpha inhibitors to indicative budget limits, but the relevance of this restriction may change under ongoing reforms
- The G-BA follows IQWiG recommendation, and Otezla receives evaluation of no added benefit for psoriatic arthritis
- IQWiG determines Cosentyx to offer no added benefit in psoriatic arthritis
- Taltz is unlikely to get an added benefit assessment in psoriatic arthritis from the G-BA
- Bibliography

ITALY

- Insights and strategic recommendations
- Delays in AIFA decisions for newly launched biologics hamper regional and local access
- Access to psoriatic arthritis medications is controlled for specialist use, but a more restrictive barrier is limited budget allocation
- Emilia-Romagna outlines therapeutic strategy for biologics in psoriatic arthritis
- Taltz will be placed in later lines of therapy in psoriatic arthritis
- Bibliography

SPAIN

- Insights and strategic recommendations
- National reimbursement decisions are not a barrier to access
- Regional access to psoriatic arthritis drug treatments varies in Spain
- Budget limitations and formulary restrictions are quoted as access barriers, with differences between
hospitals
- Risk-sharing agreements and local negotiations are used to control expenditure for biologics
- Taltz's positioning in psoriatic arthritis remains speculative
- Bibliography

UK
- Insights and strategic recommendations
- NICE approval is a key market access barrier
- Patient population restrictions and brand preference in regional formularies are the main access levers in psoriatic arthritis
- UK physicians reserve the use of biologics as a last resort for psoriatic arthritis patients
- Use of Stelara in psoriatic arthritis is reserved for after failure with TNF-alpha inhibitors
- Later biologic entrants require patient access schemes to have an acceptable ICER
- NICE does not recommend Otezla for psoriatic arthritis due to lower effectiveness than TNFalpha Inhibitors
- Biosimilars present the greatest threat to Cosentyx's chances of NICE recommendation for first-line biologic use
- Taltz is likely to receive a similar NICE recommendation to Cosentyx
- Regional formulary decisions
- SMC approves Otezla for psoriatic arthritis contrary to NICE decision due to differences in treatment sequencing
- SMC supports use of lower dose of Simponi, but higher dose is not deemed to be cost effective
- Bibliography


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.

<table>
<thead>
<tr>
<th>Product Name:</th>
<th>Psoriatic Arthritis Pricing, Reimbursement, and Access</th>
</tr>
</thead>
<tbody>
<tr>
<td>Web Address:</td>
<td><a href="http://www.researchandmarkets.com/reports/3797459/">http://www.researchandmarkets.com/reports/3797459/</a></td>
</tr>
<tr>
<td>Office Code:</td>
<td>SC</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Product Format</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic (PDF) - Single User</td>
<td></td>
</tr>
<tr>
<td></td>
<td>USD 7500</td>
</tr>
<tr>
<td>Electronic (PDF) - Enterprise</td>
<td></td>
</tr>
<tr>
<td></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

<table>
<thead>
<tr>
<th>Title:</th>
<th>Mr ☐ Mrs ☐ Dr ☐ Miss ☐ Ms ☐ Prof ☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name:</td>
<td></td>
</tr>
<tr>
<td>Email Address: *</td>
<td></td>
</tr>
<tr>
<td>Job Title:</td>
<td></td>
</tr>
<tr>
<td>Organisation:</td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td></td>
</tr>
<tr>
<td>City:</td>
<td></td>
</tr>
<tr>
<td>Postal / Zip Code:</td>
<td></td>
</tr>
<tr>
<td>Country:</td>
<td></td>
</tr>
<tr>
<td>Phone Number:</td>
<td></td>
</tr>
<tr>
<td>Fax Number:</td>
<td></td>
</tr>
</tbody>
</table>

* 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