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

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

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

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

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

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