

MARKET ACCESS CHALLENGES AND PRICING STRATEGIES OF STELERA IN EMERGING MARKETS

¹Sumith S N, ²Sagar Soni, ³Sarthak Gulyani, ⁴Pradnya Jadhav, ⁵Nikita Raj, ⁶Dr. N Rajesh Kumar
¹²³⁴⁵Post Graduate Student, ⁶Assistant Professor
¹²³⁴⁵⁶Department of Pharmaceutical Management
¹²³⁴⁵⁶National Institute of Pharmaceutical Education and Research, Hyderabad, Telangana, India

Abstract: Autoimmune diseases are a major and growing global health problem. They affect about 5–8% of the world's population and cause a lot of illness, high healthcare costs, and lower quality of life. Psoriasis, Crohn's disease, and ulcerative colitis are long-term immune-mediated conditions that need to be managed and treated for a long time, and sometimes for the rest of a person's life. Biologic therapies have changed the way we treat diseases by targeting specific immune pathways. They are more effective and have less overall toxicity than traditional treatments.

Stelara (ustekinumab) is a monoclonal antibody that targets interleukin-12 (IL-12) and interleukin-23 (IL-23). It has become an important biologic treatment for many autoimmune diseases. It has become a popular treatment choice in dermatology and gastroenterology because of its targeted mechanism of action, good safety profile, and long-lasting clinical effectiveness. However, even though ustekinumab has many benefits as a treatment, it is still very hard to get in emerging markets because of high treatment costs, limited reimbursement options, and problems with infrastructure. Biologic therapies face both opportunities and challenges in emerging markets, where disease rates are rising and healthcare systems are changing. Demand is rising because people are spending more on healthcare and becoming more aware of it, but cost and access are still major problems. Biosimilars are expected to make medicines more affordable and easier to get, but pricing strategies and policy frameworks will be very important in determining how many people use them in the future.

This review aims to critically analyze the market access challenges and pricing strategies associated with ustekinumab in emerging markets. By integrating clinical, economic, and strategic perspectives, the study highlights the gap between therapeutic innovation and real-world accessibility and provides insights into optimizing access to biologic therapies in resource-constrained settings.

Keywords: *Ustekinumab, Stelara, market access, emerging markets, India, Brazil, South Africa, biologics, cold chain, reimbursement, regulatory barriers, health equity*

1. INTRODUCTION

1.1 Overview of Ustekinumab

Stelara (ustekinumab) is a fully human IgG1 monoclonal antibody that selectively binds to the p40 subunit shared by interleukin-12 (IL-12) and interleukin-23 (IL-23), thereby inhibiting their activity. These cytokines play a crucial role in the differentiation and activation of T-helper cells, which are central to the pathogenesis of autoimmune diseases.[1] Ustekinumab blocks IL-12 and IL-23 signaling pathways, leading to reduced activation of Th1 and Th17 cells and subsequent suppression of inflammatory responses. This targeted mechanism allows for effective disease control while minimizing systemic immunosuppression.[2]

| Parameter | Details |
|-------------------------|---|
| Drug Name | Stelara (Ustekinumab) |
| Class | Human monoclonal antibody |
| Target | IL-12 and IL-23 (p40 subunit) |
| Mechanism | Inhibits Th1 and Th17 mediated inflammation |
| Route of Administration | Subcutaneous / Intravenous |
| Indications | Psoriasis, Psoriatic Arthritis, Crohn's Disease, Ulcerative Colitis |
| Dosing Advantage | Less frequent dosing (every 8–12 weeks) |
| Key Benefit | High efficacy with favorable safety profile |

Table 1: Basic Overview of Clinical Aspects of Ustekinumab

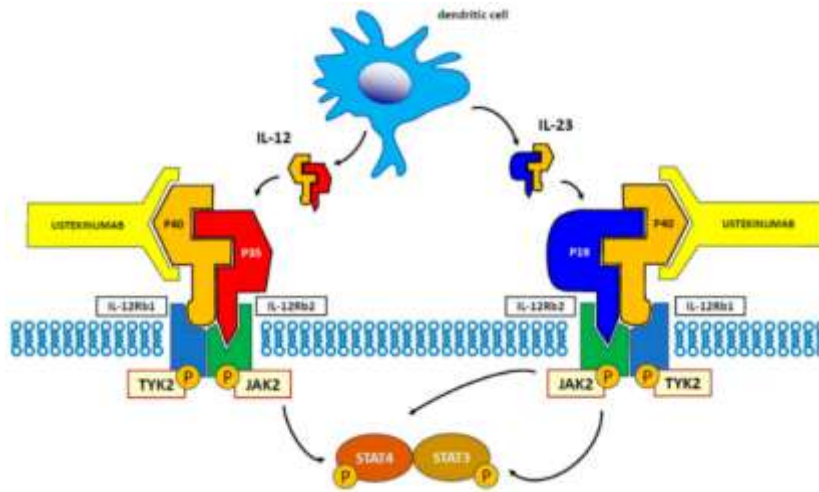


Figure 1: Mechanism of Action of Ustekinumab

1.2 Importance of Emerging Markets

Emerging markets across Asia, Latin America, and Africa are rapidly growing in the pharmaceutical sector, driven by increasing chronic diseases, improving healthcare infrastructure, and rising healthcare spending. The Asia-Pacific region is expected to see significant growth in biologic adoption due to urbanization, better diagnostics, and higher awareness. However, access to biologic therapies remains limited due to high out-of-pocket costs, low insurance coverage, and fragmented healthcare systems, leading to a gap between availability and actual use. Despite the strong clinical effectiveness of ustekinumab, its accessibility is restricted in these markets because of high costs, limited reimbursement, and infrastructural challenges.[3]

Around 40% of patients in low- and middle-income countries face affordability issues with biologics, with many discontinuing treatment due to cost. Additionally, access to advanced autoimmune therapies remains below 35% in some regions. This underscores a significant gap between innovation and accessibility, highlighting the need for better pricing strategies and policy interventions.[4]

2. REVIEW OF LITERATURE

The literature on autoimmune diseases and biologic therapies highlights a growing global burden and the increasing importance of targeted treatments. Immune-mediated inflammatory diseases have been shown to significantly impact healthcare systems and patient quality of life, necessitating effective long-term therapeutic strategies.[5]

Biologic therapies have emerged as a major advancement in the management of autoimmune diseases. Studies indicate that these therapies provide superior clinical outcomes compared to conventional treatments, particularly in patients with moderate-to-severe disease. Ustekinumab, in particular, has demonstrated strong efficacy in achieving disease remission and improving patient outcomes across multiple indications.[6]

However, the high cost of biologics has been consistently identified as a major barrier to access. Research suggests that the premium pricing of biologics limits their availability in low- and middle-income countries, leading to disparities in treatment access. In many emerging markets, limited insurance coverage and high out-of-pocket expenditure further exacerbate these challenges.[7]

The introduction of biosimilars has been widely recognized as a potential solution to improve access. Studies indicate that biosimilars can significantly reduce treatment costs and increase patient access, while maintaining comparable efficacy and safety profiles. The entry of biosimilars into the market is expected to enhance competition and drive price reductions.[8]

Market research literature highlights that the demand for biologics, including ustekinumab, is driven by the increasing prevalence of autoimmune diseases and the growing adoption of targeted therapies. Emerging markets are expected to play a crucial role in future growth due to expanding healthcare infrastructure and rising awareness.[9]

However, several barriers to market access persist, including regulatory challenges, limited reimbursement frameworks, and infrastructural constraints. These factors contribute to delayed adoption and reduced accessibility of biologic therapies in emerging markets.[10]

Overall, the literature underscores the need for a balanced approach that integrates clinical innovation with economic sustainability. While biologics such as ustekinumab offer significant therapeutic benefits, addressing pricing and access challenges is essential to ensure equitable healthcare delivery.[11]

3. Market Access Challenges

Biologic therapies have transformed the treatment of immune-mediated inflammatory diseases, with ustekinumab (Stelara®) emerging as a highly effective option for conditions like psoriasis, psoriatic arthritis, Crohn's disease, and

ulcerative colitis. Its global success is reflected in USD 10.86 billion in revenue in 2023, highlighting both strong clinical demand and commercial importance.[12]

However, a major paradox exists: despite its effectiveness, most patients in low- and middle-income countries cannot access it. This is not due to clinical limitations but because of barriers such as high pricing, weak healthcare systems, regulatory delays, and logistical challenges. Stelara’s pricing varies widely across countries, but even the lowest prices remain unaffordable in emerging markets where out-of-pocket spending is dominant. As a result, access remains severely restricted.[13]

| Country / Region | Approx. Price (USD/cycle) | Insurance Coverage | Patient Burden OOP |
|------------------|---------------------------|------------------------------|--------------------|
| United States | \$25,497 / 8 weeks | High (commercial + Medicare) | Low–Moderate |
| Switzerland | \$9,223 | High (universal) | Low |
| Germany | ~\$6,500–\$8,000 | High (GKV/PKV) | Low |
| India | \$1,222 | Limited / fragmented | Very High |
| Brazil | ~\$1,500–\$2,500 (est.) | Public SUS (selective) | High |
| South Africa | ~\$1,800–\$3,000 (est.) | Private only | Very High |

Table 2: Comparative Stelara Pricing Across Key Markets (2024 Data)

3.1 Barrier I – High Cost Barriers

3.1.1 The Economics of Biologic Manufacturing

Biologics like ustekinumab differ significantly from small-molecule drugs due to their complex production process. They are made using living cells and require advanced technologies such as bioreactors, purification systems, strict quality control, and specialized cold-chain storage. This complexity leads to much higher manufacturing costs compared to conventional drugs, making high pricing a structural feature of biologics.[14]

Even before adding R&D, regulatory, and marketing costs, the base production cost of ustekinumab is already high. Its premium pricing is further driven by its strong clinical value and limited competition from biosimilars, especially in markets lacking strong pricing negotiation systems like health technology assessment (HTA) bodies.[13]

3.1.2 Annual Treatment Cost and Per Capita Income Disparity

The affordability of ustekinumab in emerging markets is a major challenge when compared to average income levels. In India, even at a lower price of about USD 1,222 per cycle, annual treatment costs range from USD 4,900–6,000, equivalent to two to three years of average income. In Brazil and South Africa, despite higher GDP per capita, biologic therapy still imposes a significant financial burden. Access is inconsistent in Brazil’s public system and largely limited to private insurance holders in South Africa, who represent a small portion of the population.[15]

As a result, most patients face catastrophic out-of-pocket expenses, and access to biologics is largely restricted to wealthier individuals or those with insurance or special support mechanisms, highlighting severe inequality in treatment access.[14]

3.1.3 Absence of Domestic Generic or Biosimilar Competition

Biosimilars, which are key to reducing biologic drug prices, have not significantly impacted ustekinumab access in emerging markets. Although biosimilars have entered markets like the US and Europe, offering prices up to 90% lower, they primarily target high-income regions where returns are more favorable.[16]

Emerging markets face several barriers to benefiting from biosimilars. These include complex and costly regulatory approval processes in each country, making market entry less attractive. Additionally, the lack of pricing policies and substitution frameworks allows the original high-priced drug to remain dominant due to physician prescribing habits. In some regions, such as South Africa, private healthcare systems and existing agreements further limit biosimilar adoption.[15]

| Market | Originator Status | Biosimilar Approved? | Key Limitation |
|--------------|--------------------|-----------------------------|---|
| India | Approved (Stelara) | Partial / Limited | CDSCO pathway complex; limited local trial data |
| Brazil | Approved | No approved biosimilar | ANVISA biosimilar pathway underutilized for this molecule |
| South Africa | Approved (SAHPRA) | Not yet approved | Regulatory bandwidth and capacity constraints |
| USA / EU | Approved | Yes – 7+ biosimilars (2025) | Not accessible to LMICs due to pricing/distribution |

Table 3: Ustekinumab Biosimilar Approval Status in Emerging Markets (2025)

3.2 Barrier II – Insurance and Reimbursement Gaps

3.2.1 Overview of Health Financing in Emerging Markets

Access to expensive biologics largely depends on a country’s health financing system. In high-income countries, government or insurance systems absorb these costs through reimbursement and HTA-based pricing, making such therapies more accessible. However, this support is limited in emerging markets.[17]

In India, healthcare is funded through a mix of public spending, out-of-pocket payments, and private insurance, with a significant burden on individuals. Although the Ayushman Bharat (AB-PMJAY) scheme covers a large population for hospitalization, it does not adequately include high-cost biologics like ustekinumab, as it focuses mainly on procedures rather than long-term drug therapy. Private insurance coverage is also limited and often excludes biologics or comes with high premiums, further restricting access.[16]

3.2.2 Brazil: The SUS Litigation Pathway

Brazil’s healthcare system (SUS) is designed to provide universal access, but in practice, access to high-cost biologics like ustekinumab is limited. Their inclusion depends on strict evidence-based protocols and HTA approval, making availability restricted.[18]

Although ustekinumab is considered relatively cost-effective for psoriasis, its high acquisition cost significantly affects its affordability within the system. As a result, many patients resort to legal action to obtain coverage—a process that is complex, time-consuming, and not accessible to everyone.[17]

This “litigation-based access” creates inequality, favoring urban and educated patients with legal resources, while marginalized populations are often excluded. Consequently, access to biologics in Brazil remains inconsistent and inefficiently managed.[16]

3.2.3 South Africa: A Bifurcated Access System

South Africa’s healthcare system is highly unequal, with a well-funded private sector serving about 17% of the population and an underfunded public sector serving the remaining 83%. Although ustekinumab is approved, it is not included in the public sector’s Essential Medicines List and is not reimbursed, limiting access.[19]

As a result, access is largely restricted to patients with private insurance. Even within the private sector, strict requirements such as pre-authorization, step-therapy protocols, and regular reviews create delays that may worsen disease progression.[16]

While the proposed National Health Insurance (NHI) system could improve access in the future, its implementation is uncertain and currently does not guarantee coverage of biologics. Until then, most patients in South Africa remain unable to access ustekinumab due to systemic healthcare inequalities.[19]

3.3 Barrier III – Regulatory Challenges

3.3.1 Heterogeneous Regulatory Landscapes

The regulatory approval of biologic medicines in emerging markets is governed by a patchwork of national agencies, each with distinct requirements, capacity levels, and processing timelines. Unlike small-molecule generics, which can follow abbreviated new drug application (ANDA) pathways, biologics require comprehensive dossiers encompassing structural characterization, preclinical safety, pharmacokinetic studies, and often locally conducted clinical trials. For an originator product like ustekinumab, the regulatory journey in each emerging market country is largely independent of the FDA or EMA approvals already granted.[18]

3.3.2 India: CDSCO and the Biosimilar Regulatory Framework

In India, drug approvals are regulated by the CDSCO along with the Department of Biotechnology, with biosimilar guidelines aligned to global standards but including additional requirements such as mandatory post-marketing studies. While ustekinumab has been approved, its development required significant local data.[20]

For biosimilars, the approval process remains complex and often unpredictable due to limited regulatory expertise and inconsistent review timelines. Smaller patient populations for certain indications further increase the burden of clinical trial requirements.[19]

Additionally, India does not allow automatic approval of all indications based on one successful indication, unlike the US and EU. This means each indication requires separate clinical validation, delaying biosimilar entry and keeping prices high for longer.[20]

3.3.3 Brazil: ANVISA's HTA-Linked Approval Process

In Brazil, biologic drugs are approved by ANVISA, which follows internationally aligned regulatory standards. However, access involves a two-step process: regulatory approval followed by health technology assessment (HTA) and cost-effectiveness evaluation by CONITEC before inclusion in the public healthcare system (SUS).[21]

This process creates delays between drug approval and actual patient access. In the case of ustekinumab, availability in the public system depends on CONITEC's evaluation, even after regulatory approval. Although the assessment standards are similar to those in Europe, variable review timelines and capacity issues lead to uncertainty and slower access for patients.[20]

3.3.4 South Africa: SAHPRA Capacity and Reform

South Africa replaced the Medicines Control Council with SAHPRA in 2018 to reduce regulatory backlogs and improve efficiency. Earlier, approval timelines for new drugs could take 5–10 years due to a large backlog of applications.[22] Although SAHPRA has improved processes, approval of biologics remains complex and resource-intensive. South Africa does not have domestic manufacturing for biologics, so all such drugs must be imported and undergo additional regulatory and compliance checks.[21]

For biosimilars like ustekinumab, the high requirements for comparative data further increase the regulatory burden, making market entry less attractive and delaying access.[23]

3.3.5 Pharmacovigilance and Post-Marketing Gaps

A key regulatory challenge in emerging markets is weak pharmacovigilance systems for monitoring drug safety after approval. Biologics like ustekinumab carry risks such as increased susceptibility to infections, including tuberculosis, which is especially relevant in high-burden countries like India and South Africa.[24]

Effective pharmacovigilance requires strong reporting systems, trained professionals, and reliable data infrastructure. However, in many emerging markets, these systems are underdeveloped, leading physicians to perceive biologics as riskier and limiting their use even when affordable. Although regulatory bodies have introduced stricter post-marketing requirements, implementation remains inconsistent. This creates a paradox where countries that need strong safety monitoring the most are the least equipped to provide it.[23]

3.4 Barrier IV – Supply Chain and Cold Chain Issues

3.4.1 The Biologic Cold Chain: A Critical Infrastructure Requirement

Ustekinumab requires strict cold-chain storage (2°C–8°C), making reliable temperature-controlled logistics essential for its safe and effective use. This creates a major challenge in emerging markets, where supply chain infrastructure is often inconsistent.

The drug must be maintained under refrigeration throughout manufacturing, distribution, storage, and administration, with each stage posing a risk of failure. Cold-chain breaches are common globally and even more frequent in developing regions, leading to significant product loss or reduced effectiveness.

As a result, inadequate cold-chain systems act as a critical but often overlooked barrier, limiting the safe delivery and real-world accessibility of biologics like ustekinumab.[25]

3.4.2 India: Urban-Rural Divide in Cold Chain Coverage

India has a divided supply chain system. Major cities like Mumbai, Delhi, Bengaluru, Hyderabad, and Chennai have well-developed cold-chain infrastructure and specialty pharmacy networks. However, beyond these urban areas, the infrastructure weakens significantly.[26]

Rural regions, where about 65% of the population resides, face issues such as power outages, lack of refrigerated transport, limited pharmacy access, and insufficient trained personnel. Since ustekinumab requires specialized administration and monitoring, it is mostly available in urban tertiary care centers. As a result, patients from rural and semi-urban areas must travel long distances for treatment, adding indirect costs like travel, time, and lost income, which further worsen affordability and access.[27]

3.4.3 Latin America: Infrastructure Investment and Gaps

Brazil has made significant investments in cold chain infrastructure, mainly for vaccines, but this does not fully support the distribution needs of high-cost biologics like ustekinumab. Distribution of such therapies is handled through specialized centers, but their availability and cold chain standards vary widely across regions, especially in the North and Northeast where infrastructure is weaker.[22]

Additionally, Brazil relies heavily on imports for ustekinumab, as there is no domestic manufacturing for this biologic. This creates challenges such as currency fluctuations, import costs, and vulnerability to global supply disruptions.[27]

3.4.4 South Africa: Import Dependency and Distribution Challenges

South Africa's supply chain for biologics like ustekinumab is fully dependent on imports and primarily serves the private healthcare sector. Efficient cold chain systems are largely concentrated within major private hospital networks, limiting access to insured patients.[28]

In contrast, the public sector lacks adequate cold chain infrastructure and handling capabilities needed for large-scale biologic distribution. This gap reflects broader regional challenges, as cold chain logistics in Africa remain underdeveloped relative to healthcare needs. Frequent cold chain failures further highlight this issue, with significant losses of biologic products during distribution. Overall, inadequate infrastructure and reliance on private systems severely restrict access to biologics for the majority of the population.[22]

3.4.5 Compounding Factors: Power, Training, and Governance

Beyond physical infrastructure, several systemic factors compound cold chain challenges in all three markets. Reliable electricity supply is a prerequisite for cold chain maintenance, but power outage frequency in rural India, certain South African provinces, and parts of Brazil remains high. Backup power systems for pharmaceutical cold stores are often absent in public facilities. Training for pharmacy staff in cold chain handling protocols & breach documentation is frequently inadequate. Quality management systems for biologic distribution including temperature logging, batch documentation, and root-cause analysis for cold chain excursions are present in private sector institutions but are inconsistently implemented in public systems.[29]

3.5 Barrier V – Awareness and Adoption Barriers

3.5.1 The Dermatology and Gastroenterology Workforce Gap

Access to ustekinumab is further limited by the need for specialist prescribing, such as dermatologists for psoriasis and gastroenterologists for IBD. In emerging markets, the availability of these specialists is significantly lower compared to high-income countries.

In India, there are only about 0.5–0.7 dermatologists per 100,000 people and even fewer gastroenterologists, with most concentrated in urban areas. This creates large regions where patients cannot access biologic therapy due to lack of qualified specialists.

Similarly, South Africa has very low dermatologist availability, while Brazil has better numbers overall but uneven distribution, with specialists concentrated in cities like São Paulo and Rio de Janeiro.

Overall, the shortage and uneven distribution of specialists in emerging markets significantly restrict the initiation and access to biologic therapies.

3.5.2 Physician Education and Prescribing Confidence

Even when specialists are available, the use of biologics like ustekinumab is limited by gaps in training and experience. Many doctors in emerging markets were trained in settings where biologics were not commonly used, leading to low confidence in prescribing and managing these therapies.

Safety concerns, especially in high tuberculosis-burden countries, further restrict use. Although guidelines recommend TB screening before starting biologics, implementation is inconsistent across regions. Limited familiarity with monitoring and managing side effects makes physicians more cautious.

As a result, many specialists prefer conventional treatments over biologics, even when the latter may be more effective, due to risk aversion and lack of practical experience.

3.5.3 Patient Awareness and Health Literacy

Patient-level factors also significantly limit access to biologics like ustekinumab. Awareness of diseases such as Crohn's disease and ulcerative colitis is much lower in emerging markets, leading to underdiagnosis, especially in regions like India, Latin America, and South Africa.

This lack of diagnosis directly restricts access, as patients cannot receive advanced therapies without proper identification of their condition. Rural populations are particularly affected due to limited access to specialists.

Additional barriers such as language differences, reliance on traditional medicine, and distrust of injectable treatments further reduce patient demand and uptake, creating challenges even before issues like cost or infrastructure come into play.

3.5.4 The Role of Industry Patient Access Programs

Janssen has implemented patient access programs (PAPs) for ustekinumab, such as the STELARA with Me program in the US, which offers significant cost support and assistance with insurance processes. However, these programs are mainly designed for high-income markets.

In emerging markets, similar programs exist but are limited in reach, duration, and impact. They often provide only temporary support, such as short-term access or coverage while awaiting insurance approval, and are typically restricted to patients linked to major medical centers. Due to economic constraints, these programs cannot sustainably support long-term treatment for low-income patients. As a result, their overall impact on improving access in low- and middle-income countries remains limited.

3.5.5 Synthesis: Why Patients Cannot Access This Drug

The lack of access to ustekinumab in emerging markets is not due to a single issue but a combination of five interconnected systemic barriers:

Even at lower local prices, the annual cost of therapy far exceeds average incomes in countries like India, Brazil, and South Africa, making it unaffordable for most patients.

Public and private healthcare systems provide inadequate or inconsistent coverage. Government schemes often exclude biologics, while private insurance covers only a small portion of the population and includes restrictive approval processes.

Complex and time-consuming approval processes across different countries delay both originator and biosimilar entry, limiting competition and keeping prices high.

Weak cold chain and distribution infrastructure, especially outside major cities, restrict reliable delivery of the drug, even for patients who can afford it.

Low disease awareness, underdiagnosis, shortage of specialists, and limited physician experience with biologics reduce the number of patients who actually reach and receive such therapies.

The market access challenge for ustekinumab in emerging markets is systemic, driven by multiple interconnected barriers. High costs relative to income, weak reimbursement systems, complex regulatory processes, inadequate cold chain infrastructure, and low awareness together prevent most eligible patients in regions like India, Latin America, and South Africa from accessing the therapy.

Addressing this requires coordinated efforts across stakeholders. Pharmaceutical companies should adopt tiered pricing and expand access programs. Regulatory bodies need to streamline and harmonize approval processes, while governments must establish clear reimbursement policies instead of relying on litigation-based access. Investment in cold chain infrastructure should also extend beyond vaccines to support specialty drugs.

A key priority is enabling biosimilar adoption, which has already improved access in high-income markets. This involves supportive regulations, substitution policies, and transparent pricing. Overall, improving access is both a moral and commercial necessity, achievable through targeted policy reforms, industry strategies, and sustained commitment.

4. Pricing Strategies & Pharmacoeconomics of Ustekinumab in Emerging Markets

4.1 Initial Premium Pricing Strategy

Ustekinumab was launched as a breakthrough biologic targeting IL-12 and IL-23 pathways, offering strong clinical benefits for diseases like psoriasis and IBD. Due to its innovation and effectiveness, it was introduced with a premium pricing strategy, common for advanced biologics. This high pricing is driven by substantial R&D costs, complex manufacturing involving living cells, and extensive clinical trials. Its superior clinical outcomes further justify the price by demonstrating improved patient results and reduced disease burden.

In high-income countries, annual treatment costs of \$70,000–\$80,000 are supported by strong insurance systems and higher willingness to pay. However, in emerging markets, where out-of-pocket spending is high and healthcare systems are less developed, such pricing leads to significant access barriers.

As a result, while premium pricing supports innovation and profitability, it also creates major inequalities in access, especially in resource-limited settings.

4.2 Differential Pricing in Emerging Markets

Differential (tiered) pricing is used by pharmaceutical companies to adjust drug prices across countries based on economic conditions and healthcare factors. For ustekinumab, prices are lower in emerging markets like India (₹6–10 lakhs annually) compared to over \$70,000 in the United States. Pricing differences are influenced by factors such as income levels, healthcare infrastructure, insurance coverage, and regulatory policies. While this approach improves access to some extent, affordability remains a major issue in emerging markets due to high out-of-pocket spending.

Additionally, challenges like lack of price transparency and risks of parallel trade limit the effectiveness of differential pricing. Overall, although it helps, this strategy does not fully bridge the affordability gap in resource-constrained settings.

4.3 Impact of Biosimilars

The expiry of patents for biologics like ustekinumab has enabled the development of biosimilars highly similar versions in terms of safety, efficacy, and quality—significantly impacting pricing and access. Since 2023, biosimilars have entered global markets, reducing prices by 15% to 90% depending on competition.

Biosimilars improve affordability, increase market competition, expand patient access, and are often supported by government policies. In emerging markets, they are especially important as they can substantially lower treatment costs and improve accessibility.

However, their uptake depends on factors such as physician trust, regulatory processes, patient awareness, and interchangeability policies. Despite these challenges, biosimilars remain the most effective solution to address affordability issues in biologic therapies.

4.4 Cost-Effectiveness and QALY Concept

Pharmacoeconomic evaluation helps determine whether a treatment offers value for money, often using the Quality-Adjusted Life Year (QALY), which combines life expectancy and quality of life.

$$\text{QALY} = \text{Life Years Gained} \times \text{Quality of Life Weight}$$

Ustekinumab provides significant clinical benefits, including better disease control, fewer relapses, and improved quality of life, leading to higher QALY gains.

In high-income countries, where willingness-to-pay thresholds are high, the drug is often considered cost-effective. However, in emerging markets, lower thresholds, limited HTA frameworks, high out-of-pocket costs, and constrained healthcare budgets make it less economically viable.

Thus, despite strong clinical value, ustekinumab is often not considered cost-effective in these settings, creating a gap between its medical benefits and affordability.

4.5 Value-Based Pricing

Value-based pricing links the cost of a drug to the outcomes it delivers, ensuring that healthcare systems pay based on treatment effectiveness rather than a fixed price. For ustekinumab, this can be tied to factors like clinical remission, improved patient-reported outcomes, and reduced long-term healthcare costs.

This approach helps maximize value and minimizes spending on ineffective treatments. However, in emerging markets, its implementation is challenging due to weak data systems, limited payer capabilities, administrative complexity, and difficulties in tracking long-term outcomes. Despite these limitations, value-based pricing has strong potential to improve access and make healthcare spending more efficient in the future.

4.6 Tender-Based Procurement

Tender-based procurement is a key strategy used in emerging markets to improve access to expensive therapies by purchasing drugs in bulk through competitive bidding, which helps reduce prices. Countries like India and Brazil use this system for biologics in public healthcare.

Its advantages include lower costs through economies of scale, improved access for underserved populations, and better pricing transparency. However, challenges remain, such as supply chain inefficiencies, bureaucratic delays, limited rural availability, and reliance on selected suppliers.

While highly effective especially when combined with biosimilars its success depends on strong governance and efficient supply chain systems to ensure consistent drug availability.

5. Competitive Landscape of Stelara (Ustekinumab)

Stelara (ustekinumab), developed by Johnson & Johnson, is a pioneering biologic for treating immune-mediated diseases like psoriasis and IBD. Its dual action on IL-12 and IL-23 provided a strong clinical advantage over earlier therapies, positioning it as a premium and widely accepted treatment.

However, since patent expiry after 2023, the competitive landscape has changed significantly. Stelara now faces competition from newer biologics with improved targeting and from lower-cost biosimilars, especially in cost-sensitive emerging markets.

As a result, competition is no longer based only on clinical efficacy but also on pricing, accessibility, and healthcare policies. Stelara must now balance innovation with affordability to remain competitive.

The competition can be categorized into

5.1 Competition from Next-Generation IL-23 Inhibitors

Next-generation IL-23 inhibitors, particularly Skyrizi and Tremfya, pose a major competitive threat to Stelara. Unlike Stelara, which targets both IL-12 and IL-23, these therapies selectively inhibit the IL-23 pathway, offering more precise immune modulation.

This targeted approach improves efficacy and safety by avoiding interference with IL-12, which is important for normal immune function. Clinically, IL-23 inhibitors achieve higher skin clearance rates (PASI 90/100), longer remission periods, and better outcomes in conditions like psoriasis and IBD.

From a market perspective, these drugs are rapidly gaining adoption, especially in developed countries where clinical performance drives treatment choices. In emerging markets, their use is growing in urban private healthcare settings despite higher costs.

Overall, IL-23 inhibitors represent an innovation-driven threat, often viewed as next-generation therapies that are gradually replacing Stelara in treatment protocols, particularly in dermatology.

5.2 Competition from Anti-TNF Therapies

Anti-TNF therapies like Humira and Simponi remain key competitors to Stelara, especially in emerging markets. Although they are older biologics, their long-standing clinical use and well-established safety profiles have built strong physician trust.[31]

Their biggest advantage is affordability, driven by the availability of multiple biosimilars, particularly for adalimumab. This makes them more accessible and positions them as first-line biologic treatments in many healthcare systems.

Step-therapy protocols further reinforce their use, requiring patients to try these lower-cost options before moving to newer, more expensive treatments like Stelara. As a result, Stelara is often used as a second- or third-line therapy, limiting its reach.[33]

5.3 Competition from IL-17 Inhibitor

IL-17 inhibitors such as Cosentyx and Taltz are strong competitors to Stelara, particularly in dermatology. They target the IL-17 pathway and are highly effective in treating psoriasis.

Their main advantage is a rapid onset of action, providing faster symptom relief and achieving high levels of skin clearance, making them a preferred choice for moderate-to-severe psoriasis.[18]

However, their use is limited in gastrointestinal conditions, as they are less effective in Crohn's disease and may even worsen symptoms. This gives Stelara an advantage in broader indications. Strategically, IL-17 inhibitors compete mainly in the psoriasis segment, reducing Stelara's market share in dermatology, especially among patients seeking quick and highly effective results.[13]

5.4 Competition from Oral Therapies

Oral small-molecule therapies like Otezla provide an alternative to biologics, competing with Stelara through convenience and affordability. As an oral PDE4 inhibitor, Otezla eliminates the need for injections, making it more attractive to patients who prefer non-invasive treatment options.[34]

It is also relatively less expensive than biologics, improving accessibility. However, its efficacy is generally lower, especially in severe cases, so it is mainly used for mild-to-moderate disease or as an initial therapy before moving to biologics. Strategically, oral therapies act as indirect competitors by reducing the number of patients who eventually require biologics, thereby shrinking the potential market for high-cost treatments like Stelara[22]

5.5 Biosimilars: The Most Disruptive Competitive Force

Biosimilars such as Wezlana, Selarsdi, and Otulfi represent the most significant shift in Stelara's competitive landscape. These products are clinically equivalent in terms of efficacy, safety, and quality. Their key impact lies in drastically lower pricing often 70–90% cheaper than the originator—which shifts competition from innovation to affordability and access. This makes them highly attractive to healthcare systems, insurers, and patients, especially in cost-sensitive emerging markets.[35]

Adoption is further supported by government policies, reimbursement frameworks, and public procurement programs. Major players like Amgen, Samsung Bioepis, and Celltrion are driving this space with strong manufacturing and global reach. Strategically, biosimilars pose a direct substitution threat, offering the same clinical outcomes at much lower costs, thereby putting strong downward pressure on Stelara's pricing and market share.[36]

6. Case Studies: Stelara (Ustekinumab) in Emerging Markets

6.1 India Case Study

India is a highly price-sensitive pharmaceutical market with a large patient base and rising autoimmune diseases. Despite strong clinical outcomes, biologics like Stelara have limited adoption due to affordability issues and weak reimbursement. Growth in the biologics market is driven by better awareness, diagnostics, and private healthcare, but access is mainly restricted to urban tier-1 cities. Stelara is priced at ₹1.5–2.5 lakh per dose, with annual costs exceeding ₹10–15 lakh. High out-of-pocket spending, limited insurance coverage, and lack of government reimbursement make it accessible only to affluent patients.[37]

Availability is largely confined to corporate hospitals and private clinics in metro cities like Mumbai, Delhi, Hyderabad, and Bangalore. Rural and semi-urban areas face shortages of specialists, infrastructure, and awareness, further limiting access.[37]

India lacks a strong reimbursement framework for biologics. Schemes like Ayushman Bharat focus on hospitalization rather than chronic therapies. There is limited insurance inclusion and no centralized biologics policy, though biosimilar policies[37] are supportive.

Indian companies like Biocon and Dr. Reddy's Laboratories are expected to introduce lower-cost biosimilars, which will reduce prices, expand access, and influence prescribing patterns.

India is a cost-driven market where affordability dominates decision-making. Stelara is likely to remain a niche, specialist-driven therapy concentrated in private healthcare, while biosimilars are expected to drive future growth and accessibility.[37]

6.2 China Case Study: Stelara (Ustekinumab) in an Evolving, Policy-Driven Market

China is a large and rapidly growing pharmaceutical market, with rising autoimmune diseases due to urbanization and lifestyle changes. Stelara plays an important role in treatment, but market adoption is strongly influenced by government policies rather than just clinical benefits. Drug pricing is tightly controlled through systems like the National Reimbursement Drug List and volume-based procurement programs. Inclusion in NRDL improves access but requires major price cuts (40–70%), reflecting strong government bargaining power.[38]

Access has improved due to expanded insurance coverage and NRDL inclusion, reducing patient costs and increasing uptake. Urban centers like Beijing, Shanghai, and Guangzhou have better infrastructure and specialist care, while rural areas still face limited access and awareness. The National Medical Products Administration has accelerated approvals through fast-track pathways and acceptance of global data. However, reimbursement approval remains the key factor for success. China's healthcare reforms emphasize affordability and access through insurance expansion, biosimilar

promotion, and centralized procurement.[39] While these improve access, they also impose strict pricing pressure. Prescribing is influenced by clinical outcomes, hospital policies, and reimbursement. Stelara is mainly used for moderate-to-severe or treatment-resistant cases due to cost and formulary constraints. Patients remain price-sensitive, even with insurance support, and are increasingly open to switching to biosimilars based on cost and physician advice. Stelara is positioned as a high-efficacy therapy for complex cases but faces pressure from pricing regulations, biosimilars, and newer biologics. Success depends on pricing negotiations, reimbursement inclusion, and physician engagement. Major challenges include price reductions, strong biosimilar competition, reliance on reimbursement systems, and urban-rural disparities in healthcare access. [40]

7. Conclusion

As competition intensifies from newer biologics and biosimilars, Johnson & Johnson has adopted multiple strategies to maintain Stelara's market position by addressing pricing pressure, clinical competition, and access challenges. Patient Assistance Programs (PAPs) offer co-pay support, discounts, and starter doses to improve affordability and adherence, especially in emerging markets. Stelara has expanded its indications from psoriasis to Crohn's disease and ulcerative colitis, increasing its patient base. Its long dosing interval (8–12 weeks) provides a convenience advantage. The company uses differential pricing and negotiates with governments for reimbursement inclusion (e.g., National Reimbursement Drug List), shifting from high-margin to volume-driven growth. Medical education programs and collaborations with key opinion leaders help maintain physician trust and prescribing preference. Stelara is positioned as a clinically proven and reliable biologic with strong long-term evidence, helping retain patients despite cheaper biosimilars. Initiatives like CarePath focus on education, affordability, and treatment support, enhancing patient experience and loyalty.

8. References

- [1] Johnson & Johnson. (2024). Annual Report 2023: Pharmaceutical Segment Performance. Johnson & Johnson, New Brunswick, NJ. Available at: investor.jnj.com
- [2] Managed Healthcare Executive. (2025). Two More Stelara Biosimilars Launch, Including One That Is 90% Off Stelara. Managed Healthcare Executive. managedhealthcareexecutive.com. Accessed April 2026.
- [3] Coherent Market Insights. (2024). Stelara Market Size, Opportunities & YoY Growth Rate, 2032. Coherent Market Insights. coherentmarketinsights.com. Accessed April 2026.
- [4] MetaTech Insights. (2025). Ustekinumab Market Forecast & Epidemiology Insights 2025–2035. metatechinsights.com. Accessed April 2026.
- [5] Drug Patent Watch. (2025). Drug Prices and Trends for Stelara (Ustekinumab). drugpatentwatch.com. Accessed April 2026.
- [6] GoodRx Health. (2025). How Much Is Stelara Without Insurance? GoodRx Inc. goodrx.com. Accessed April 2026.
- [7] Research and Markets. (2025). Stelara (Ustekinumab) Market Report 2025: Epidemiology, Pipeline Analysis, Market Insights & Forecasts 2019–2034. Globe Newswire. May 2025.
- [8] Bioprocess International. (2025). Strategic Global Market Access: The Role of Health Technology Assessments in Navigating Access Barriers for Biopharmaceuticals. BioProcess Int. bioprocessintl.com. March 2025.
- [9] World Health Organization. (2025). Biosimilars: Expanding Access to Essential Biologic Therapies. WHO. who.int. February 13, 2025.
- [10] Drug Channels. (2025). The Stelara Biosimilar Price War: How PBM-Affiliated Private Labels Are Reshaping the Market. drugchannels.net. October 2025.
- [11] Janssen Pharmaceuticals. (2025). STELARA Access & Support. stelarahcp.com. Accessed April 2026.
- [12] Janssen Pharmaceuticals. (2025). Cost & Insurance | STELARA. stelarainfo.com. Accessed April 2026.
- [13] Archana S., et al. (2024). Regulatory Requirements for Biosimilars in India: A Review Article. International Journal of Biological & Pharmaceutical Allied Sciences (IJBPAS). 2024 December. DOI: ijbpas.com.
- [14] Patel A., et al. (2018). Biologics Use in Indian Psoriasis Patients. Indian Dermatology Online Journal. PMC5134162. PubMed Central.
- [15] Biosimilars in India: Current Status and Future Perspectives. (2019). PMC. Journal of Pharmacology & Pharmacotherapeutics. PMC6394151.
- [16] BioSpectrum India. (2024). Why India Must Turn Biosimilar Powerhouse by 2030. biospectrumindia.com.
- [17] Precedence Research. (2024). Psoriasis Biosimilars Market Size, Share & Growth Forecast 2024–2034. precedenceresearch.com.
- [18] InsightAce Analytic. (2024). Psoriasis Biosimilars Market: New Trends 2024–2031. insightaceanalytic.com.
- [19] Visiongain. (2024). Biosimilars and Follow-On Biologics Market Report 2024–2034. visiongain.com.
- [20] Single Care. (2024). How Much Is Stelara Without Insurance? singlecare.com. Accessed April 2026.
- [21] Emery C.A., et al. (2019). Market Access Analysis of Biologics and Small-Molecule Inhibitors for Inflammatory Bowel Disease Among US Health Insurance Policies. PubMed. PMID: 30923985. Inflamm Bowel Dis. 2019 Dec.

- [22] Sibbald C., et al. (2025). Biosimilars Versus Biological Therapy in Inflammatory Bowel Disease: Challenges and Targeting Strategies Using Drug Delivery Systems. PMC. PMC11972199. 2025 January.
- [23] ScienceDirect. (2023). Delivery of Biologics: Topical Administration. Biomaterials. 2023 Sep. doi:10.1016/j.biomaterials.2023.122185.
- [24] PMC. (2021). Grand Challenges in Pharmaceutical Research Series: Ridding the Cold Chain for Biologics. Frontiers in Pharmacology. PMC7869771. 2021.
- [25] Emergen Research. (2025). Healthcare Cold Chain Logistics Market Size, Share & Growth Report 2024–2034. emergentresearch.com.
- [26] MarketIntel. (2025). Cold Chain Logistics for Biologics Market Research Report 2033. marketintel.com.
- [27] Menter A., et al. (2014). Cost-Effectiveness of Biologic Agents in the Treatment of Moderate-to-Severe Psoriasis: A Brazilian Public Health Service Perspective. Value in Health Regional Issues. Nov 2014. ScienceDirect.
- [28] PharmiWeb. (2025). Anti-Inflammatory Biologics Market Set to Reach USD 182.5 Billion by 2033: FutureWise Research. pharmiweb.com. October 2025.
- [29] National Psoriasis Foundation. (2025). Biosimilars for Psoriasis and Psoriatic Arthritis. psoriasis.org. Accessed April 2026.
- [30] Persistence Insights. (2025). Top 10 Psoriasis Drug Companies Revolutionizing Patient Care. persistenceinsights.wordpress.com. July 2025.
- [31] World Bank. (2024). World Development Indicators: GDP per Capita, India, Brazil, South Africa. data.worldbank.org. 2024.
- [32] Ministry of Health and Family Welfare, India. (2023). Ayushman Bharat – Pradhan Mantri Jan Arogya Yojana (AB-PMJAY) Annual Report 2022–23. pmjay.gov.in.
- [33] National Department of Health, South Africa. (2023). National Health Insurance Bill. Government Gazette. No. 48884. 2023.
- [34] CONITEC (Comissão Nacional de Incorporação de Tecnologias no SUS). (2023). Relatório de Recomendação: Ustekinumabe para Psoríase Moderada a Grave. Brazilian Ministry of Health.
- [35] SAHPRA. (2023). South African Health Products Regulatory Authority: Biologic Medicine Registration Guidelines. sahpra.org.za.
- [36] ANVISA. (2022). Resolução da Diretoria Colegiada – RDC N° 204: Regulamento Técnico para Medicamentos Biológicos. ANVISA, Brazil.
- [37] CDSCO & DBT. (2016). Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India. 2nd Edition. Ministry of Health and Family Welfare, India.
- [38] Open PR. (2025). Stelara (Ustekinumab) Industry Report 2025–2034: Market Dynamics, Drivers, and Forecasts. openpr.com. June 2025.
- [39] BisResearch. (2025). How Are Innovative Biologics and Biosimilars Reshaping the Global Psoriasis Treatment Landscape? bisresearch.com. October 2025.
- [40] Globe Newswire. (2025). Stelara (Ustekinumab) Market Report 2025: Epidemiology, Pipeline Analysis, Market Insights & Forecasts 2019–2024. Globe Newswire. May 9, 2025.

Copyright & License:



© Authors retain the copyright of this article. This work is published under the Creative Commons Attribution 4.0 International License (CC BY 4.0), permitting unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.