BRAND ACCESS MARKETPLACE DYNAMICS: AUTOIMMUNE

Summary

A private, ongoing, multi-client study.

June 2020

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This summary provides highlights from robust longitudinal insights reports released throughout the year and available at our INTELLICENTER® portal. The Brand Access Marketplace Dynamics reports identify current and future access landscapes providing insights to support effective identification of opportunities and risks for autoimmune brands.

Methodology

Marketplace Dynamics Autoimmune Research Methodology

Health Strategies Insights™ by EVERSANA conducts ongoing **longitudinal** research on U.S. marketplace trends, customer needs, and access barriers and opportunities for biopharmaceutical companies within the Autoimmune market

Your team will have access to our **subject matter experts** and opportunities for inquiries and input into research, as well as tailored presentations on opportunities and risks for your specific pipeline and inline Autoimmune drugs

Online surveys & follow-up interviews of **pharmacy and medical directors at health plans, IDNs, medical groups and PBMs***, to provide quantitative benchmarking data and qualitative insights into best practices, skill sets, and future outlook

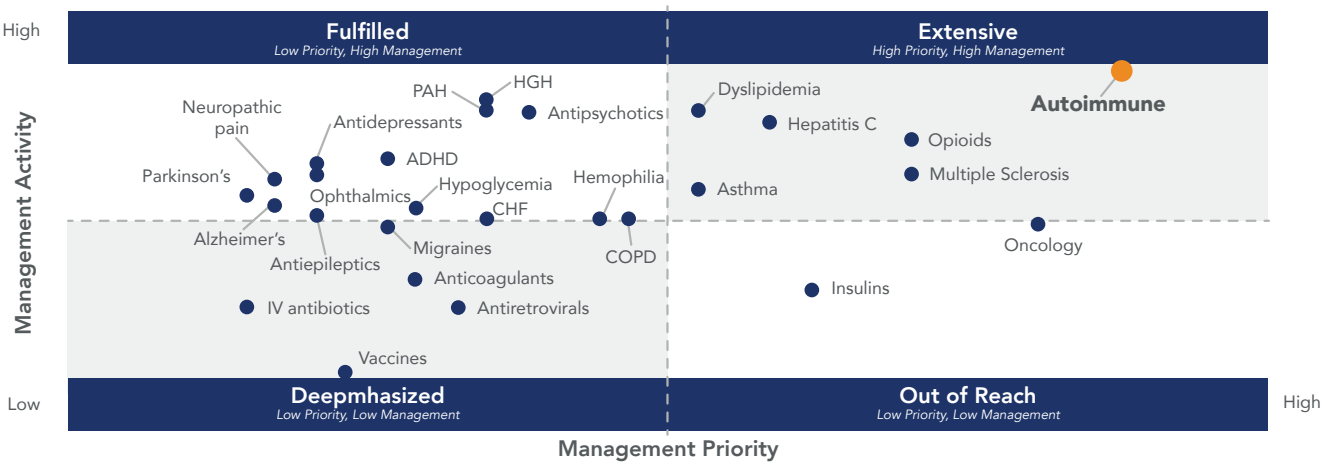
*Refer to the research agenda for sample size and detailed profile

KEY FINDINGS	IMPLICATIONS & RECOMMENDATIONS
The autoimmune market continues to be a top management priority, receiving the highest management attention across stakeholders through formulary and utilization management tactics.	Biopharmaceutical companies must continue to remain competitive with aggressive pricing and contracting strategies as the overall market and individual classes continue to crowd. In addition to drug pricing, brands able to demonstrate improvements to the overall cost of care for patients will prove meaningful to payers as they try to manage this high cost, and largely commoditized, market.
As classes crowd, stakeholders begin to make decisions by indication or within mechanisms of action (e.g., selecting a preferred IL-17 or JAK inhibitor).	Interclass competition is fierce, and payers will take advantage of every opportunity to leverage one drug against another. Building specific and highly targeted value propositions to differentiate from the competition, or entering into shared-risk arrangements, will help to increase or ensure access.
Beyond net pricing, national physician associations are one of the largest external influencers on 2020 autoimmune drug access and prescribing decisions. However, stakeholders are increasingly considering other external sources, such as third-party health economics and outcomes research [HEOR] studies and reports from the Institute for Clinical and Economic Review [ICER]).	Autoimmune brand strategies must continue to consider the influence physician association recommendations (e.g., American Academy of Rheumatology, American College of Gastroenterology, American Academy of Dermatology) can have on drug visibility and demand, but also weigh the secondary influencers beginning to have a greater hold in the market. While current industry-sponsored HEOR studies continue to lack the level of authority needed to make major access decisions, if a biopharmaceutical company can successfully prove credibility in this space via partnerships, it will gain a significant advantage.
The increased crowding of the autoimmune market, especially within newer classes (e.g., JAK inhibitors, IL inhibitors), prompts payers to increasingly segment and manage access decisions by class and/or mechanism of action.	Biopharmaceutical companies must be prepared for drug class–level decisions and align their access tactics to meet payers' autoimmune access management goals and strategies as many move away from indication-level decisions. This hypercompetitive contracting environment will continue, and companies with new entrants or those seeking additional indications should consider a two-pronged approach: focusing aggressively on value-based contracting and promoting clinical benefits to drive utilization away from in-class rivals.
Lacking superior clinical differentiation, new brands entering increasingly crowded classes will face additional access hurdles (e.g., cost-sharing exposure from formulary management, strict prior authorizations requiring multiple trials of preferred drugs).	It is critical for biopharmaceutical companies to aim to distinguish their products in their class, align with payers on how they are currently segmenting the market, and then design contracting strategies highlighting this approach.
Payers target biopharmaceutical company cost-sharing support programs to drive formulary adherence and patient decisions.	In 2020, nearly a quarter of payers actively block at least some copay cards, and 38% use copay accumulator tools. Companies must look to other tactics, such as debit cards and direct reimbursement checks, to continue their patient cost-sharing support outside of formulary placement.

KEY FINDINGS	IMPLICATIONS & RECOMMENDATIONS
Management intensity and cost-sharing exposure continues to increase for infusible and injectable products under the medical benefit as payers seek to contain costs across the spectrum of care.	Biopharmaceutical companies should approach cost sharing for medical-benefit drugs as they do for pharmacy-benefit drugs, considering cost-sharing support programs, contracting for preferred status, or even partnering on disease management programs that waive copays for adherence. Companies with office-administered drugs must have discussions with both pharmacy and medical departments to determine all potential utilization tactics and access barriers their drugs will encounter; these will drive the necessary access strategies.
Aligning with payers, providers increasingly segment autoimmune drugs by class/mechanism of action when making access and prescribing decisions. However, many organized providers still consider the whole category and/or by indication, creating the potential for misalignment with payers' formularies and desired utilization.	Companies should develop clear strategies to differentiate their products from others in the same class/using the same mechanism of action. Depending on the strengths of the drug, strategies should emphasize clinical superiority, ability to reduce total costs, and/or contracting. Companies can support providers on issues resulting from misalignment between provider and payer formularies.
Providers remain sensitive to payer tactics and nearly always align their own drug management tools with payer formularies.	Companies should continue to optimize their products' presence on payer formularies and communicate that presence to medical groups and health systems. Companies should update providers on payers' evolving policies, help them navigate access barriers, and provide resources to help mitigate the administrative burden resulting from payer management tactics.
Although providers typically give their physicians flexibility in treatment decisions, most do require medical rationale for going off protocol. Drug management tactics are often communicated through electronic medical records (EMRs) and their use encouraged through education from clinical pharmacists.	Companies with off-protocol drugs will benefit from providing resources to make the process of going off protocol easier for prescribers and staff. Companies should work to ensure inclusion of relevant data in provider EMRs and communicate key product differentiators to clinical pharmacists at provider organizations.
Most of the reimbursement within the auto-immune market is volume based; however, providers predict a significant shift toward value-based reimbursement in the near future.	Companies should provide evidence that their products can assist providers in meeting value-based objectives by showing clinical efficacy, immediate cost savings, or decreases in total cost of care.

Autoimmune Brands Face Extensive Access Barriers

Autoimmune is the most prioritized and managed therapeutic category. Relative to other drug classes, current and future autoimmune brands face extensive access barriers.



N=40 health plans. Source: Health Strategies Insights by EVERSANA, Brand Access Marketplace Dynamics, January 2020.

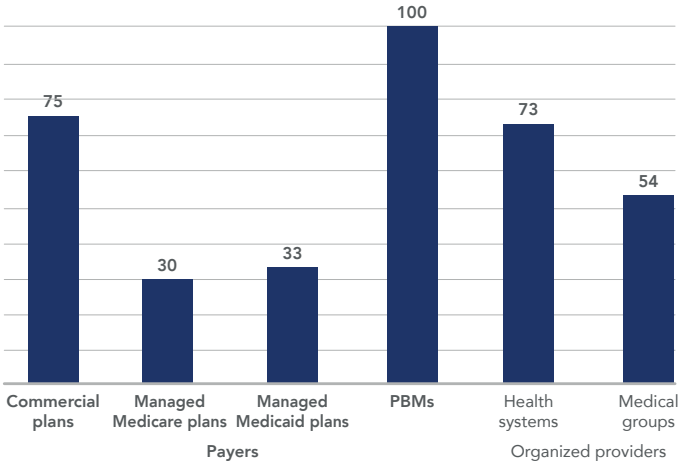
Health Plans & PBMs Seek Cost Savings for Autoimmune Treatment Options

To reduce cost, commercial plans' PBMs and Health Systems continue to scrutinize Autoimmune treatment options. Commercial plan customers continue to demand aggressive contracts from autoimmune brands, as this class of therapy remains one of the most highly managed in the industry; competitive pricing is table stakes for all brands – old and new.

As most government plans have already instituted strict management controls over autoimmune drug access, they instead tend to prioritize other, less controlled categories to reduce overall costs.

Payers and Providers Continue to Prioritize Management of Autoimmune Products

(Percentage rated managment priority high across 30+ markets)



N=40 health plans, N=5 PBMs, N=40 health systems, N=26 medical groups.
Source: Health Strategies Insights by EVERSANA, Brand Access Marketplace Dynamics, January 2020.

> **From a commercial perspective we continue to manage this category and products aggressively, PAs, step edits through preferred agents. Medicare less so, everything is specialty tier simply because of cost. There are no stepping or preferred drugs.**
>
> *– National Pharmacy*

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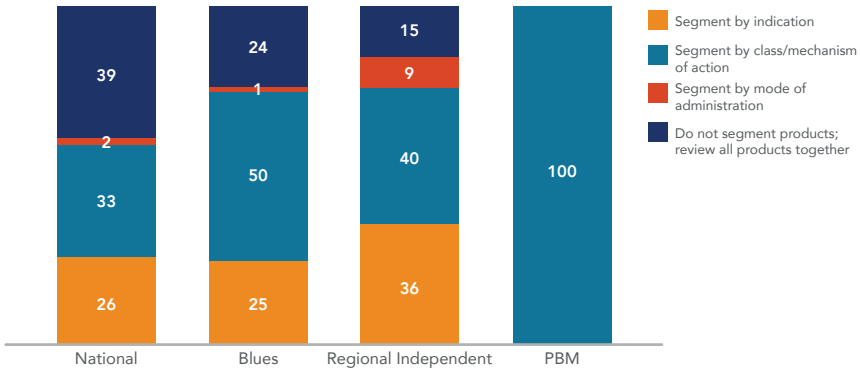
Payers Look to Market Access Decisions to Leverage on Competition and Drive Savings

Payers look at market access decisions within drug classes to leverage intraclass competition and drive savings. Biopharmaceutical companies must be prepared for class-level decisions and align their access tactics to meet payers' autoimmune access management goals and strategies as many move away from overall autoimmune-level decisions.

PBMs, more than plans, have moved away from the "all in one bucket" approach and are fully embracing segmentation by class, posing even greater risk for brands not able to distinguish themselves from direct competitors.

This hypercompetitive contracting environment will continue, and companies with new entrants or those seeking additional indications should consider a two-pronged approach: focusing aggressively on value-based contracting and promoting clinical benefits to drive utilization away from in-class rivals.

Big Shift Away from Indication for Blues and Regional Plans in Segmenting the Autoimmune Market
(Percentage enrollment)



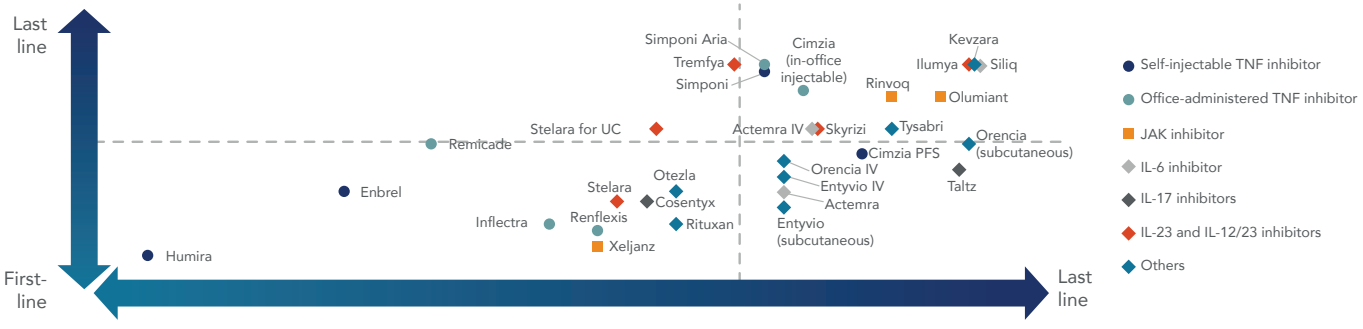
Source: Health Strategies Insights by EVERSANA, Brand Access Marketplace Dynamics, February 2020.

Line of Therapy Assignments by Brand Align Across Payers and Providers

TNF Inhibitors remain first-line choice, but new competition has led to preferred brands within other classes. Humira and Enbrel retain the best access in the autoimmune market due to market tenure, market share, and aggressive contracting.

However, the influx of new drugs/classes has driven better access for other class leaders (e.g., Xeljanz, Inflectra, Stelara, Cosentyx). Since launch, Remicade biosimilars Inflectra and Renflexis have made access and prescribing gains, especially with organized providers.

Line of Therapy Assignments by Brand Align Across Payers and Providers



N=37 health plans, N=40 health systems. Source: Health Strategies Insights by EVERSANA, Brand Access Marketplace Dynamics, January 2020.

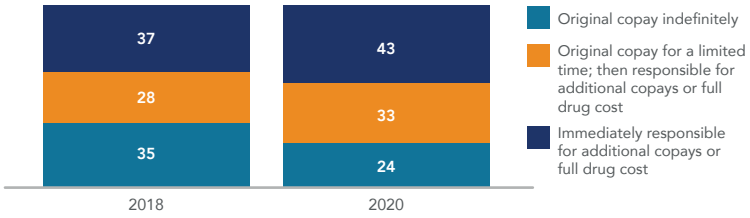
Fewer Plans and PBMs Allow Grandfathering of Nonpreferred or Excluded Autoimmune Drugs

The decline of grandfathering policies creates additional opportunities for newer drugs to build market share through preferred status with payers. This increases the importance of launch strategies, including competitive pricing and contracting terms

Pharmaceutical companies with autoimmune brands should be aware of individual plans' grandfathering policies in order to better align strategic initiatives and address potential risks to their brands' formulary status.

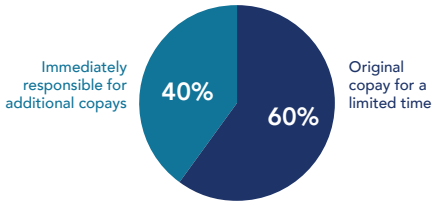
Historically, the requirement to grandfather patients had a significant impact on plan formulary decisions; the continued entrance of new drugs lacking clinical differentiation encourages payers to manage access to preferred formulary options.

Almost Half of Plans Make Patients Immediately Responsible for High Copays Upon Formulary Change as Grandfathering Policies Erode
(Percentage plans)



2018 N=40 health plans, 2020 N=37 health plans

PBMs Refrain from Grandfathering Policies in Autoimmune
(Percentage enrollment)



N=5 PBMs

Source: Health Strategies Insights by EVERSANA, Brand Access Marketplace Dynamics, February 2020.

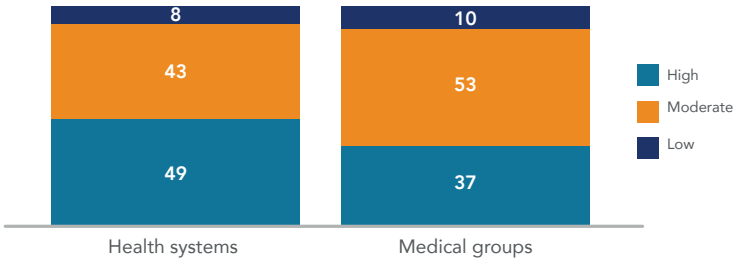
Organized Providers Align to Payer Formularies to Reduce Administrative and Patient Financial Burdens

Perceptions of limited clinical differentiation and the potential for high out-of-pocket (OOP) costs for patients encourage organized providers to limit administrative burdens and align to payer autoimmune formularies as much as possible.

While specialists are very familiar and comfortable with appealing payer access barriers for their patients (especially those that have failed previous therapies), they are more likely to prescribe preferred first-line options for treatment-naïve patients.

New autoimmune brands entering the market must take a multipronged approach, proving superior clinical efficacy relative to competitors to gain specialist support and entering into aggressive pricing/ contracting agreements to achieve preferred access with payers.

Systems Report Higher Levels of Alignment to Payer Formularies than Groups
(Percentage providers indicating level of alignment)



N=37 health systems, N=19 medical groups.
Source: Health Strategies Insights by EVERSANA, Brand Access, Marketplace Dynamics - Autoimmune, April 2020.

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> **We check on their plan and give the patient an approximation of what their cost would be. Using that as the determining factor if they wanted to decide if that is the treatment they want to start.**
>
> *– Medical Group Director*

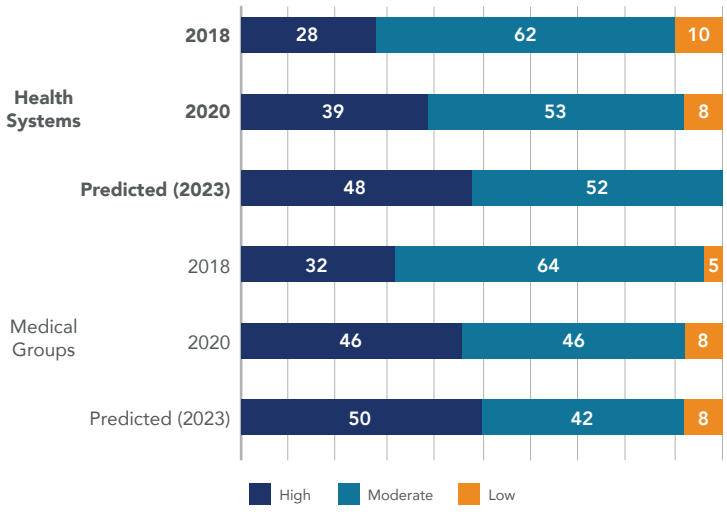
Patient Costs Impact Prescribing Decisions

Healthcare providers tend to be sensitive to patient costs when prescribing a specific medication, reinforcing the need for preferred payer access and patient financial support. Autoimmune brands must ensure optimal access via payer formularies, but they must also develop and promote patient financial support services that minimize OOP costs, such as copay cards or appeals and denials assistance programs.

As some payers look to minimize the utilization and impact of copay card programs through outright blocking and accumulator solutions, autoimmune companies must be aware of each payer's policies and be targeted in their tactics.

Medical groups, which typically see and treat patients more often, are slightly more sensitive to patient OOP costs. Coupled with their continued involvement with alternative payment models (APMs) that hold them to quality metrics (e.g., adherence, patient satisfaction), this can lead groups to look to minimize disruption of therapy from access barriers and/or high patient costs.

Patient Cost Sharing and OOP Costs Will Increasingly Impact Prescribing Decisions by 2023
(Percentage providers indicating level of impact)



N=40 health systems, N=26 medical groups. Source: Health Strategies Insights by EVERSANA, Brand Access, Marketplace Dynamics - Autoimmune, April 2020.

About EVERSANA™

EVERSANA is the leading independent provider of global services to the life science industry. The company's integrated solutions are rooted in the patient experience and span all stages of the product lifecycle to deliver long-term, sustainable value for patients, prescribers, channel partners and payers. The company serves more than 500 organizations, including innovative start-ups and established pharmaceutical companies to advance life science solutions for a healthier world. To learn more about EVERSANA, visit EVERSANA.COM or connect through LinkedIn and Twitter.