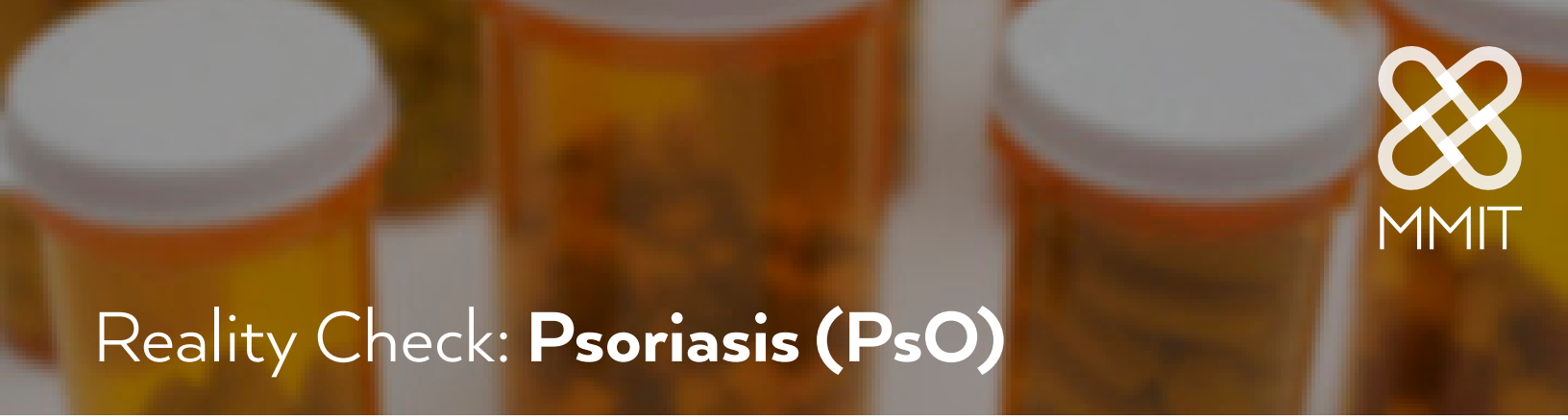
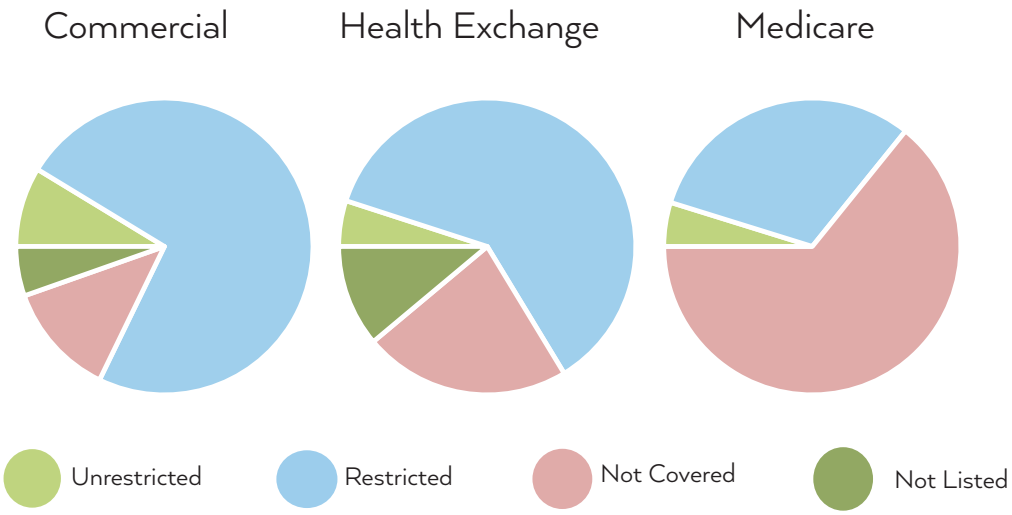


Reality Check: **Psoriasis (PsO)**

Coverage

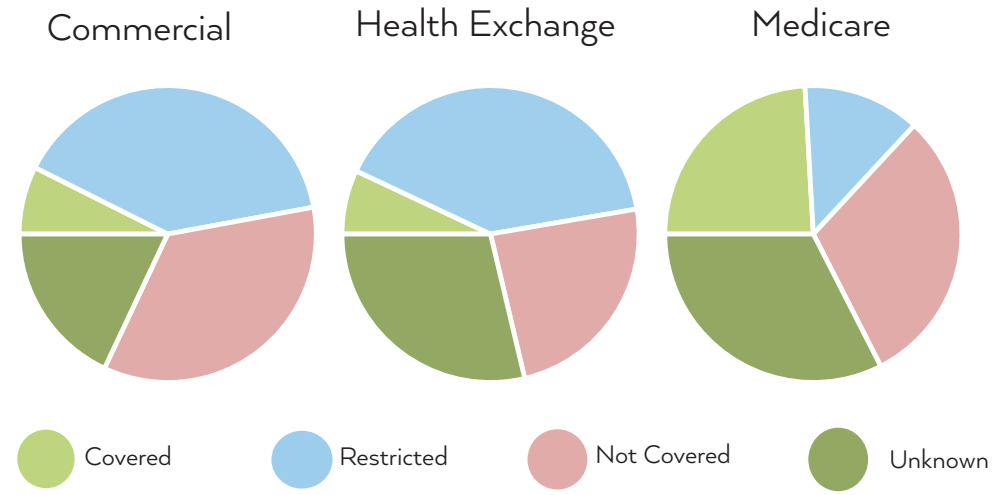
Pharmacy Benefit

Under the pharmacy benefit, almost 74% of the lives under commercial formularies are covered with utilization management restrictions. Around 64% of the lives under Medicare pharmacy benefit formularies are not covered for at least one of the drugs.



Medical Benefit

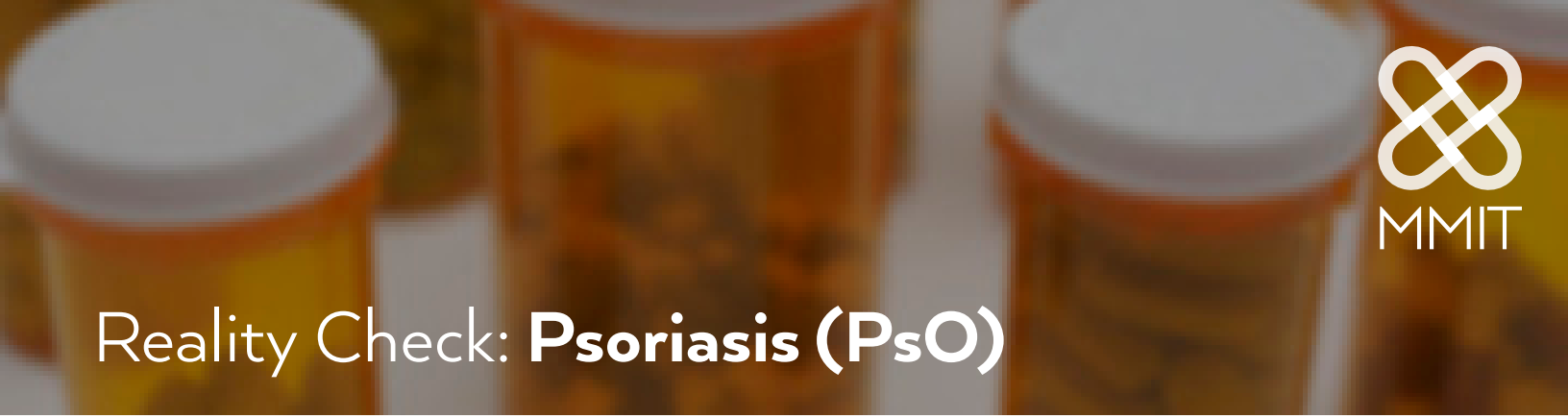
Under the medical benefit, about 40% of the lives under commercial and health exchange policies are covered with utilization management restrictions. More than 24% of Medicare beneficiaries have access to the medications without restrictions.



Key Players

abbvie AMGEN Celgene Johnson & Johnson Pharmaceutical Research & Development, L.L.C. Lilly

Merck Novartis Pfizer Sun Pharma ucb Valeant Pharmaceuticals International



Reality Check: **Psoriasis (PsO)**

Trends

FDA Approved Hadlima

In July 2019, the FDA approved Samsung Bioepis Co., Ltd.'s Hadlima (adalimumab-bwwd) for the treatment of plaque psoriasis, rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult Crohn's disease and ulcerative colitis. It is the fourth biosimilar of AbbVie Inc.'s Humira (adalimumab) that the agency has approved. Merck & Co., Inc. will commercialize the drug in the U.S. It is expected to launch after June 30, 2023.


Exclusive Subscriber Content RADAR on Specialty Pharmacy

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New FDA Specialty Approvals

Aug 1, 2019

✦ ***June 28: The FDA approved Thiola EC*** (tiopronin) in combination with high fluid intake, alkali and d prevention of cystine stone formation in adults and pediatric patients weighing at least 20 kg with severe cystinuria. The drug from Retrophin, Inc. is a new enteric-coated formulation of Thiola, which the FDA ir The recommended starting dose of the new tablet differs between adults and pediatric patients. Websit of 30 tablets of 100 mg Thiola EC as more than $840. Visit www.thiola.com.

✦ ***July 3: The FDA gave accelerated approval to Karyopharm Therapeutics Inc.'s Xpovio*** (selinex dexamethasone for the treatment of adults with relapsed or refractory multiple myeloma who have rece therapies and whose disease is refractory to at least two proteasome inhibitors, two immunomodulatory CD38 monoclonal antibody. Dosing for Xpovio is 80 mg via four 20 mg tablets on days one and three of wholesale acquisition cost is $22,000 per month. Visit www.xpovio.com.

✦ ***July 4: The FDA approved Grifols' Xembify*** (immune globulin subcutaneous human-klhw) to treat immunodeficiency disease in people at least two years old. Dosing and dosing intervals for the subcuta based on a patient's serum IgG trough level and weight. The company says it plans to launch the thera 2019. For more information, visit www.xembify.com.

Subscribers to AIS's *RADAR on Specialty Pharmacy* may read the in-depth article online

FDA Approved AbbVie's Injectable Skyrizi

In April 2019, the FDA approved AbbVie Inc.'s injectable Skyrizi (risankizumab-rzaa) for the treatment of plaque psoriasis. AbbVie's Hurima pen is one of the most advantaged therapies for the treatment of plaque psoriasis, holding preferred status for 9% of covered lives, which grows to 60% including prior authorization and step therapy.


Datapoint: FDA Approved AbbVie's Injectable Skyriz

Apr 30, 2019

The FDA last week approved AbbVie's injectable Skyrizi for the treatment of plaque psoriasis. AbbVie's Humira pe the most advantaged therapies for the treatment of plaque psoriasis, holding preferred status for **9%** of covered liv grows to **60%** including prior authorization and step therapy. AbbVie may soon be reckoning with an onslaught of competition to Humira, as the drug's patent expired in Europe at the end of 2018.

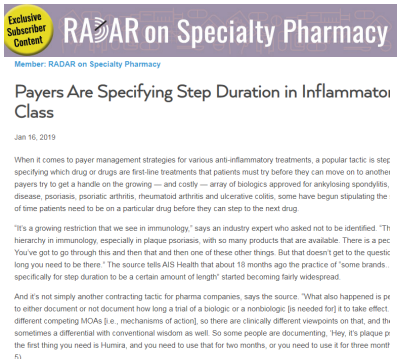
SOURCE: MMIT Analytics, as of 4/26/19

Datapoint
Drug Benefits

Via AIS Health

Payers Specify Step Duration

As payers try to get a handle on the growing and costly array of biologics approved for psoriasis and other inflammatory conditions, some have begun stipulating the specific length of time patients need to be on a particular drug before they can step to the next drug. "It's a growing restriction that we see in immunology," says an industry expert. "There is a hierarchy in immunology, especially in plaque psoriasis, with so many products that are available."


Exclusive Subscriber Content RADAR on Specialty Pharmacy

Member: RADAR on Specialty Pharmacy

Payers Are Specifying Step Duration in Inflammato Class

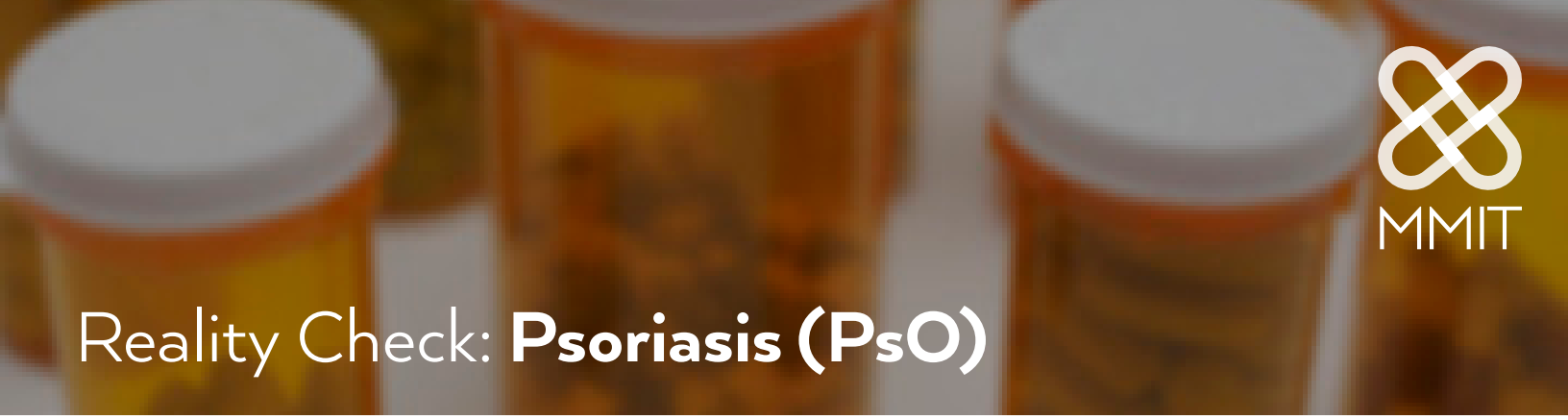
Jan 16, 2019

When it comes to payer management strategies for various anti-inflammatory treatments, a popular tactic is step specifying which drug or drugs are first-line treatments that patients must try before they can move on to another payers try to get a handle on the growing — and costly — array of biologics approved for ankylosing spondylitis, disease, psoriasis, psoriatic arthritis, rheumatoid arthritis and ulcerative colitis, some have begun stipulating the of time patients need to be on a particular drug before they can step to the next drug.

"It's a growing restriction that we see in immunology," says an industry expert who asked not to be identified. "Th hierarchy in immunology, especially in plaque psoriasis, with so many products that are available. There is a pec You've got to go through this and then that and then one of these other things. But that doesn't get to the questic long you need to be there." The source tells AIS Health that about 18 months ago the practice of "some brands.. specifically for step duration to be a certain amount of length" started becoming fairly widespread.

And it's not simply another contracting tactic for pharma companies, says the source. "What also happened is pe to either document or not document how long a trial of a biologic or a nonbiologic [is needed for] it to take effect. different competing MOAs [i.e., mechanisms of action], so there are clinically different viewpoints on that, and th sometimes a differential with conventional wisdom as well. So some people are documenting, 'Hey, it's plaque p the first thing you need is Humira, and you need to use that for two months, or you need to use it for three month

Subscribers to AIS's *RADAR on Specialty Pharmacy* may read the in-depth article online



Reality Check: **Psoriasis (PsO)**

Key Findings

Market Events Drive Changes

In July 2019, the FDA approved Samsung Bioepis Co., Ltd.'s Hadlima (adalimumab-bwwd) for the treatment of plaque psoriasis, among other conditions. It is the fourth biosimilar of AbbVie Inc.'s Humira (adalimumab) that the agency has approved. In April 2019, the FDA approved AbbVie's injectable Skyrizi (risankizumab-rzaa) for the treatment of plaque psoriasis.

Competitive Market Landscape

Manufacturers with franchises across inflammatory indications often hold contracting power and improved position, which is everything in this market. While a tumor necrosis factor (TNF) inhibitor is nearly always the first-line biologic after generics, there are situations where others (like Janus kinase inhibitors) have been placed on this tier. The entrance of interleukin inhibitors in recent years, with more on the way, means the desire to move past a TNF agent for better efficacy is something plans protect against and occasionally embrace. The sheer volume of products and manufacturers with products in this class, coupled with the relatively high number of possible patients, means that contracting competition is enormous.

Medical and Pharmacy Benefit Implications

Many products are covered under both the medical and pharmacy benefits, with even infusions covered under the pharmacy benefit. Cost sharing on the specialty tier is common with patient support available.

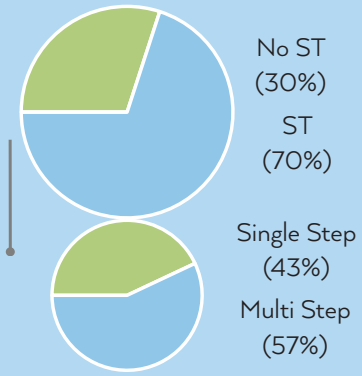
Characteristics

Indications

Psoriasis (PsO)

Step-Therapy (ST) Policies

A review of ST policies for payer-controlled formularies:



Prior-Authorization (PA) Policies

A review of PA policies for payer-controlled formularies: