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# SPECIALTY PHARMACY NEWS

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## Psoriasis Can Have Significant Health Impact; Plan Understanding May Be Lacking

While many payers may be loath to put restrictions on specialty therapies for certain conditions such as oncology, plans' approach to psoriasis often may be on the other end of the management spectrum. While more and more research is showing that it is a devastating disease linked to several comorbid conditions, some plans incorrectly view this chronic immunologic skin condition as simply a cosmetic problem. Most plans have some kind of management tools such as step therapy or prior authorization in place for biologic psoriasis therapies. But when plans do not have an accurate understanding of the disease, this can lead to overly stringent — and even unrealistic — requirements that effectively discourage patients from taking these therapies that oftentimes are the best option.

"We recognize psoriasis is a disease that can have a very significant impact on peoples' lives," says Sean Karbowicz, Pharm.D., manager of clinical pharmacy for Regence BlueCross BlueShield of Oregon. "We do not consider psoriasis to be a cosmetic problem."

According to Steve Chaffee, senior vice president of business development at Diplomat Specialty Pharmacy, psoriasis can impact a patient's quality of life on not just a physical level but also on social and psychological levels. "I don't think most plans realize what patients and their families live with," he tells *SPN*.

As many as 7.5 million Americans have psoriasis, according to the National Institutes of Health. The majority of these people have plaque psoriasis, but they may also have another form — guttate, pustular, inverse or erythrodermic — or more than one of these forms. No one knows exactly what causes psoriasis, but it is believed to have a genetic component. It can range from mild to moderate to severe, and its severity is determined by what percentage of the body is affected. It usually appears in relatively young people, often between the ages of 15 and 35.

While psoriasis itself is not a life-threatening disease, many of the conditions associated with it are. A recent article in the *Journal of American Academy of Dermatology* cites studies showing that people with more severe psoriasis seem to have increased frequency of cardiovascular disease, hypertension, obesity, diabetes

and other immunologic diseases. They also have an increased risk of depression and alcoholism, as well as an "excess risk of mortality." And according to the National Psoriasis Foundation, as many as 30% of psoriasis patients also develop psoriatic arthritis.

A variety of treatments are available for patients, and their efficacy is often tied to the severity of the disease. Most treatment regimens start with topical medications, and then move to phototherapy, then systemic therapies and then biologics. While some patients with milder forms of the disease may respond to topical medications, many others do not.

According to Chaffee, psoriasis treatments range greatly in price:

- ◆ **Topicals: \$15-\$40 per month.**
- ◆ **Phototherapy: \$20-\$50 per copayment, with treatments two or three times per week.** Some plans, he says, purchase light boxes for patients, and these generally cost \$2,300.
- ◆ **Systemics: \$80 per month.**
- ◆ **Disease-modifying antirheumatic drugs: \$700 per month.**
- ◆ **Biologics: \$18,000 or more per year.**

But when plans consider the treatments, they should not focus on the cost but rather on what the most effective therapy for that patient is, experts agree. According to the National Psoriasis Foundation, psoriasis patients lose about 56 million work hours annually, and between \$1.6 billion and \$3.2 billion is spent treating the disease.

According to the American Academy of Dermatology, "Studies confirm that the chronic physical symptoms that plague patients with moderate to severe psoriasis can be successfully alleviated with biologics, and they also are credited with helping improve a patient's quality of life." A recent survey, *Treatment-Trends: Psoriasis III*, from BioTrends Research Group, Inc., shows that the surveyed dermatologists have increased their prescribing of biologics for psoriasis (see charts, p. 3).

"For a large segment of patients, biologics are equal or better as an option," says **Eric Auger**, a partner with consulting firm Putnam Associates. But, he

says, "it is not a degenerative disease," so it's sometimes hard to make an argument for biologics.

Psoriasis is treated by many of the same drugs as are similar immunologic conditions — rheumatoid arthritis (RA), psoriatic arthritis, ankylosing spondylitis, Crohn's disease and lupus — with many more drugs in the pipeline. Self-injected Humira (adalimumab), Enbrel (etanercept) and Remicade (infliximab) are often available under the pharmacy benefit, while infused Amevive (alefacept) and Raptiva (efalizumab) are usually covered under the medical benefit. Enbrel, says **Ricky Joshi**, a consultant with Putnam, is the market leader among commercial plans, although Humira seems to be gaining ground among the dermatologists surveyed for the BioTrends report (see chart, this page). Remicade, he says, has good use among Medicare patients.

"The pipeline looks very robust," maintains Chaffee. The drug that appears to be closest to hitting the market is Centocor, Inc.'s injectable drug ustekinumab. A therapy in a new class of drugs, it was submitted to the FDA last December for the treatment of psoriasis. In June, an FDA

committee unanimously recommended its approval, and it could be approved this year. It requires as few as four doses annually (as opposed, for example, to twice-weekly and biweekly dosing with some of the other drugs), and clinical trial results have shown that it could be more effective than therapies already on the market. But as with most drugs, including other psoriasis treatments, it is not without safety risks. Still, **Joshi** says, "it looks like that product will be superior to what we currently have."

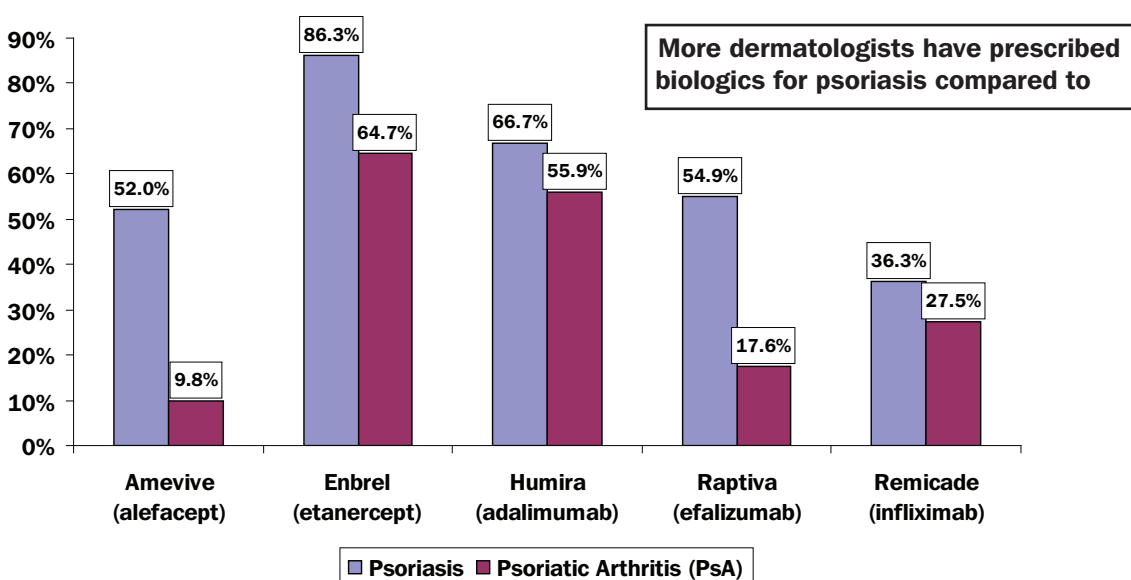
Ed Pezalla, M.D., national medical director of Aetna Pharmacy Management, says that Aetna does not have any edits, step therapy or precertification requirements for psoriasis drugs. The plan also screens for depression and refers patients for treatment.

Most of the other payers that spoke with *SPN* about their coverage of psoriasis biologics had step therapy or prior authorization in place. Some of them have Enbrel and Humira on their formularies as preferred therapies, and some require that patients try the self-injectable drugs before they try the infusibles. Most of the therapies have to be reauthorized after a few months.

### Biologic Products Used in Psoriasis and PsA

The majority of dermatologists have prescribed Enbrel for psoriasis, about two-thirds of them have prescribed Humira, and about half have prescribed Amevive and Raptiva. Remicade is prescribed by fewer dermatologists.

Percentage of Dermatologists Prescribing Each Drug



SOURCE AND METHODOLOGY: BioTrends Research Group, Inc., *TreatmentTrends: Psoriasis III*, June 2008. Research was completed between May 12 and May 17, 2008. Respondents had to have seen a minimum of 25 psoriasis patients in the past month and had to have been in practice between two and 30 years. Maximum participation by state was managed to ensure appropriate geographic distribution. Information was gathered through an online survey, with 102 respondents participating.

"I've seen a lot of differences in health plans with their coverage," says Chaffee. "Sensitivity to psoriasis patients may not be as high as it should be....It is a devastating disease." He tells SPN that he has seen plans, for example, that require patients to be 100% compliant with their therapy, a rate that is practically unheard of with any patient set. Some plans require that patients on an initial course of biologics show improvement after three months, or the drug will not be reauthorized. The problem with this, Chaffee says, is that "it sometimes takes three months, and it sometimes takes up to six months for the medication to work." Other plans may allow biologics to be used for only a limited amount of time, even when they are still proving effective. And even when plans require patients to go through numerous other therapeutic options before they can try a biologic, this process can take six months to a year, during which time the patient's condition could potentially worsen from stress that he or she is under.

"I've heard of these types of plans," says Pezalla, who says they are often requested by self-insured employers. "We don't have any self-insured employers who have such plans, and we don't promote them. I'm not sure how it works — this doesn't square with our approach of being member-centric....If you think about it, this [approach] is counterproductive."

High copays, says Auger, also can impact treatment decisions. "Twenty percent to 25% of the time when a patient refuses therapy on biologics, it is because of the [out-of-pocket] cost."

Ultimately, says Chaffee, "product choice should be guided by patient response."

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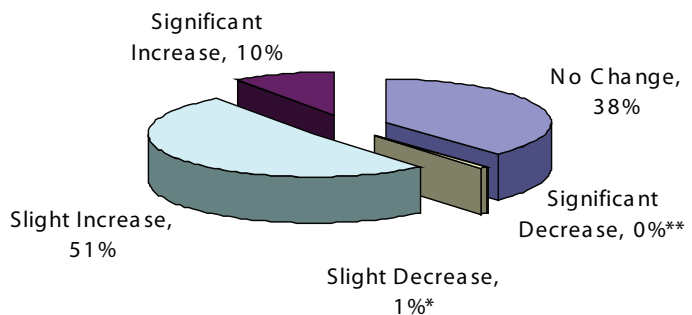
### Recent Change in the Use of Biologics to Treat Psoriasis

The majority of dermatologists responding to a spring 2008 survey said that they had recently increased their use of biologics to treat psoriasis. In the BioTrends Research Group, Inc. report *TreatmentTrends: Psoriasis III*, 61% of dermatologists surveyed in May said they had increased their use of biologics to treat psoriasis over the past six months. They cited a variety of reasons, including more familiarity with the drugs and the drugs' efficacy, as well as the January FDA approval of Humira (adalimumab) for use in adult patients with moderate to severe chronic plaque psoriasis (SPN 2/08, p. 6). For more information, contact Jennifer Robinson of BioTrends at (610) 363-3872.

#### Reasons for Increase in the Use of Biologics in the Past Six Months

| Reasons for Increase                 | N = 61 |
|--------------------------------------|--------|
| More Familiarity/Comfort             | 17     |
| More Efficacy                        | 17     |
| FDA Approval of Humira               | 15     |
| Safety                               | 11     |
| Patient Satisfaction/Comfort/Request | 10     |
| More Biologic Options                | 6      |
| More Patients                        | 5      |
| Better Coverage                      | 4      |
| Easy Dosing                          | 3      |
| Company Support                      | 2      |
| No Lab Monitoring                    | 1      |

#### Use of Biologics in the Past Six Months



\* Only one respondent reported a "slight decrease," attributing it to the "black-box" warning for Enbrel.

\*\* No respondents reported a "significant decrease."

SOURCE AND METHODOLOGY: BioTrends Research Group, Inc., *TreatmentTrends: Psoriasis III*, June 2008. Research was completed between May 12 and May 17, 2008. Respondents had to have seen a minimum of 25 psoriasis patients in the past month and had to have been in practice between two and 30 years. Maximum participation by state was managed to ensure appropriate geographic distribution. Information was gathered through an online survey, with 102 respondents participating.