A Year In Psoriasis Treatment: Looking Back, Moving Forward

From lobbying efforts to new drug approvals, the outlook for psoriasis patients may be brighter in 2006.

By Ted Pigeon, Associate Editor

From the increased use of biologics to the first new topical treatment approvals in years, the approach to psoriasis management is clearly shifting. Efforts are also underway to ensure that issues such as insurance coverage and access to care keep pace with clinical developments. Meanwhile, the search is on for even more advanced therapeutic interventions. As a new year approaches, perhaps the best way to assess where developments in psoriasis are headed over the next 12 months is to look back on the year that was.

Legislative Efforts

Despite recent advancements, many improvements must be made regarding psoriasis awareness, patient care and treatment, and ultimately finding a cure for psoriasis, says Sheila Rittenberg, Director of Advocacy of the National Psoriasis Foundation. When it lobbies on Capitol Hill on February 27, 2006, the Psoriasis Foundation will unveil its legislative agenda in hopes of acquiring more funding from the Federal government for psoriasis research and providing patients with better access to the various treatments now approved. "Our goal is for Congress to understand psoriasis and engage its members to start the process of awareness," says Ms. Rittenberg.

"The National Institutes of Health (NIH) spent roughly one dollar per American with psoriasis on psoriasis research each year over the last decade," Ms. Rittenberg notes. "We need to change that and ensure that psoriasis is up to par with other diseases and up to the times."

Apart from spreading general awareness about psoriasis, Ms. Rittenberg stresses that the Foundation intends to bring to the attention of Congress the problems currently facing doctors and patients. The second part of its three-pronged agenda deals specifically with enhancing the quality of care for patients, including improving insurance policies. "We need to work to get patients better access to treatments, but it is difficult with often restrictive insurance policies and Medicare issues recently," she remarks. "The burden of cost is shifting more and more to the patient."

To support efforts at insurance change, the Psoriasis Foundation also intends to petition the Government Accounting Organization (GAO) for a review of private sector insurance in hopes of uncovering policies to be targeted for change.

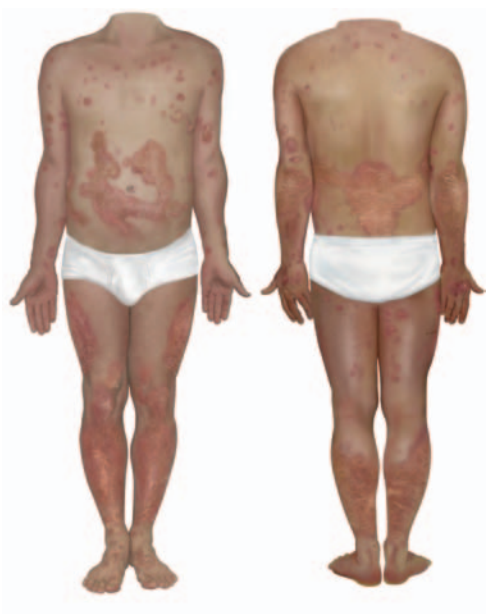
In addition to its February lobbying effort, the Psoriasis Foundation will support a "Dear Colleague" letter to the Secretary of Health and Human Services, Mike Leavitt, which according to Ms. Rittenberg, will "articulate the concerns of patients and those in the medical profession regarding psoriasis, insurance polices and access to treatments."

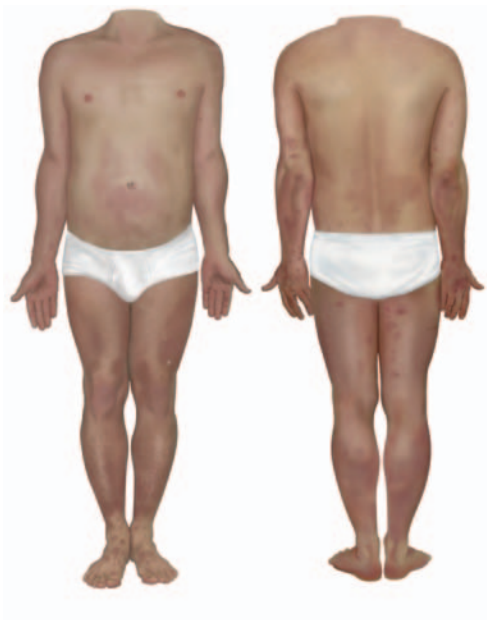
The legislative agenda addresses an overall concern of the Psoriasis Foundation regarding federal funding for psoriasis. "More work must be done in understanding the mechanism of the disease," Ms. Rittenberg says. "Genetics alone will not bring us closer to a cure—we must also attempt to understand the mechanism of psoriasis and the cause of inflammation." The Psoriasis Foundation is looking for more funding for psoriasis research and to bring attention to the disease itself. "We want Congress and the Federal Government to shift the focus of research and funding in the direction of psoriasis so that we can get closer to a cure," says Ms. Rittenberg.

Despite acknowledging that much work still needs to be done, Ms. Rittenberg remains optimistic for future treatments, research, and finding a cure for psoriasis. Referring to psoriasis as the "consistently inconsistent disease," Ms. Rittenberg feels that doctors and patients need access to a range of options while longer-term research is underway to find a permanent method of control.

Insurance Wins

There have already been some positive developments regarding insurance coverage and possibly increased patient access to psoriasis therapies. This summer, United Healthcare and Oxford Health Plans, two major insurance providers, announced that they would cover medically necessary treatment of psoriasis using PhotoMedex's XTRAC system, he first FDA approved laser treatment for psoriasis.





Illustrations, provided by Centocor, help to visualize what a PASI 90 improvement (right) from baseline (left) could look like.

Although the laser has been approved and used for psoriasis for several years, the insurance coverage program did not commence until July 2005. Some patients previously rejected treatment and some physicians failed to embrace the technology due to the lack of reimbursement. As a result of these new policies, PhotoMedex now expects the use of XTRAC to increase.

"Most major insurance companies now recognize the importance of this treatment alternative, as well as the clinical data supporting its efficacy, and have adopted favorable insurance coverage for its use for psoriasis," says Stewart Jaffe of Procyte/PhotoMedex. "Patients with psoriasis deserve and expect that proven and accepted treatments for psoriasis such as the XTRAC laser be covered by their insurance plans."

Also, changes to Medicare that permit the use of chemotherapy administration codes for IV and IM administration of therapies regardless of the diagnosis could lead to better reimbursements for those who administer biologic therapies. We reviewed these changes in the August 2005 issue (Coding Checklist, p. 14, available at www.practicaldermatology.com).

Therapeutic Developments

The past several months have yielded numerous approvals for various psoriasis treatments. Perhaps most encouraging about the growing list of approvals is the diversity of new drugs, ranging from topical sprays to biologics given by infusion. Alan Menter, MD, chair of the Division of Dermatology at Baylor University Medical Center in Dallas, offers his views on the recently approved treatment options as well as what's on the horizon for psoriasis treatment.

Topical Treatments. "Recently there has been a resurgence of interest in topical treatments," says Dr. Menter, which is widely welcome given the absence of any new formulations in the last few years and the general lack of attention paid to topicals.

First came last month's FDA approval for Clobex Spray (clobetasol propionate, Galderma), which Dr. Menter says, "is significant simply because we have not had any topical agents in 10 years." Clobex Spray 0.05% is the only available super-high potency corticosteroid non-aerosol spray formulation, according to Galderma. It is available by prescription in a 2 fl oz. bottle, and is indicated for twice-daily application to lesions. In a recent study, 78 percent of patients were clear or almost clear after four weeks of treatment with Clobex Spray. While clobetasol has been around for decades, the new non-aerosol spray formulation represents a novel application option.

The other significant development on the topical front is the anticipated US approval of an investigational formulation combining calcipotriene with betamethasone dipropionate. Now available individually, the Vitamin D3 analog helps regulate and inhibit cell growth, while the corticosteroid helps manage inflammation. According to Dr. Menter, the combination product is currently the number one prescribed topical agent in Europe , where it is marketed as Daivobet. Developer LEO Pharma and US Marketer Warner-Chilcott expect the FDA to approve calcipotriene/betamethasone dipropionate and hopes to begin marketing the product in the US during the second quarter of 2006. As a two-in-one formulation, calcipotriene/betamethasone dipropionate is "the best of both worlds and will be a major player in the topical market," notes Dr. Menter.

With so much attention drawn to

the biologic agents in the past few years, comparatively less "exciting" topicals simply didn't garner much interest until now. Importantly, Dr. Menter points out, "biologics have raised the profile of psoriasis," leading to increased attention to the disease from patients and from the medical community. Dr. Menter is pleased by the recent developments in the topical arena and hopes that this spark of interest will emphasize the ongoing development of even more advanced topical treatments.

Systemic Treatments. Two recent biologic approvals have further expanded this therapeutic avenue. The first is Humira (adalimumab, Abbott), which was approved for the treatment of psoriatic arthritis about two months ago. Previously approved for rheumatoid arthritis, Humira is anticipated to receive approval for skin disease within 18 months. "One-year data is very positive," Dr. Menter says, adding that approval of Humira for psoriasis could come by the end of 2006.

The other major biologic recently approved for psoriatic arthritis is Remicade (infliximab, Centocor) "Remicade has yielded the most dramatic response rate we've ever seen," Dr. Menter says. "Not only are the results excellent, but nearly two thirds of patients maintain those results at the end of one year." Dr. Menter anticipates that Remicade will be approved for skin disease next summer, suggesting that its popularity and use may not dramatically increase until then. The agent is provided via in-office infusions, a significant difference from other biologic agents, but experienced clinicians suggest that it can be easily adapted into practice.

Data (IMPACT 2) reported at the American College of Rheumatology Annual Meeting last month show that use of infliximab for psoriatic arthritis (PsA) inhibited radiographic progression of PsA as early as 24 weeks with continued improvement evident beyond one year. Further analysis of data showed the treatment produced significant improvements in function and quality of life, maintained beyond one year. IMPACT data reported at the conference show that 31 percent of treated patients experienced a major clinical response after 98 weeks of treatment versus zero percent of controls.

Centocor announced last month that the FDA accepted a supplemental biologics license application (sBLA) for the use of Remicade for patients with moderate to severe plaque psoriasis. While the availability of so many biologic agents could be overwhelming for physicians as decision-makers, Dr. Menter feels the options represent a patient care benefit. "It's really great to be able to offer these TNF agents," he says. "It individualizes treatment and gives patients and physicians choices, and the market will grow because of it."

But not all the news regarding systemics has been good. Since the FDA rejected Allergan's oral retinoid Tazoral (tazarotene) last fall—citing the need for a more comprehensive program to limit access and ensure safe use to avoid teratogenic effects—Allergan has been working to bolster its proposed patient education/access program to ensure women of childbearing potential do not get pregnant while on the drug. However, early last month, Allergan announced it had officially halted its clinical program for the drug, something Ms. Rittenberg describes as a "major setback" for systemic psoriasis treatments.

Making Progress

Though the abandonment of Tazoral is a disappointment, the recent approvals of new topical and biologic agents offers patients and physicians cause for optimism. If the lobbying efforts of the Psoriasis Foundation yield success, more attention and effort will be given to the need for more treatment options for psoriasis.

New in Your Practice

Lasting Results. Enbrel plus methotrexate may provide patients with rheumatoid arthritis and joint damage effective and lasting control. Amgen and Wyeth recently announced results from a long-term blinded study of anti-TNF agents RA demonstrating that more than three quarters of patients treated with Enbrel plus methotrexate therapy experienced improvement in physical function and no progression of joint damage in three years. The study was presented at the American College of Rheumatology's Annual Scientific Meeting in San Diego.

AD Will Be MIA. With the potential to restore skin health without influencing the immune system, Mimyx, a topical non-steroidal treatment from Steifel, represents a new option for AD management. Recently approved by the FDA, Mimyx restores natural structure and components of the stratum corneum, while relieving signs and symptoms of AD without adversely affecting the patient's immune system, the company says.

Don't Drink and Treat. Patients using topical tacrolimus who develop an unusual rash might consider alcohol as the cause. A recent report (Annals of Allergy, Asthma, and Immunology, 95: 291- 292) suggests three tacrolimus-treated patients developed cutaneous reactions to alcohol consumption. After discontinuing tacrolimus treatment, the response to alcohol disappeared within two weeks.

Low-Down on Lotion. PharmaDerm's recent launch of Cutivate (fluticasone propionate) Lotion 0.05% provides a new alternative for management of atopic dermatitis in patients one year of age or older. According to the company, Cutivate is the only emollient-rich mid-potency steroid lotion formulation. It is indicated for once-a-day dosing.