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Cost-Effective Psoriasis Treatment May Demand Creative Coverage Rules

While biologic agents can be costly, a new formulation of an old treatment can mean inexpensive and effective relief

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A recent *Wall Street Journal* editorial was titled "Health Care or a House." It discussed the fact that an average house payment is approximately the same as the cost of the annual health insurance premium, largely borne by employers, and suggested that employers might wish to provide a free house to their employees instead of health care insurance.

Why? The annual house payment and the annual insurance premium would be about the same amount, but the house payment would be fixed for 30 years, whereas the health care insurance premium would double every few years. A similar argument could be made for the treatment of psoriasis. The annual cost of a biologic agent is actually more than the average annual house payment used as a sample in the *WSJ* article. What if a new formulation of an old topical steroid used in combination with another old technology, ultraviolet light, offered considerable savings with the same or better outcome?

Psoriasis affects about two percent of the entire population. It is not a homogeneous disease; wide variations in its expression have been noted with some people having just a few "red spots" and others having life-threatening levels of disease. It is a chronic relapsing disease that consists of red, scaly thick skin lesions and is associated with arthritis in a small fraction of afflicted patients. It is typically symmetrical and affects the scalp, ears, elbows, knees, umbilicus, intertriginous areas and, at times, the nails, palms, and soles. Although there are four distinct presentations, the pathology for all appears to be the same: superficial perivascular infiltrates, epidermal hyperplasia, parakeratosis, exocytosis of neurrophils, and dilated capillaries.

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Costs of the disease are estimated to be $2 billion to $4 billion per year in the United States.

Treatment varies based on the severity of the disease. Localized treatment include tar derivatives, corticosteroids, calcipotriene (Dovonex), tazarotene (Tazorac), and anthralin. Systemic therapies include methotrexate, cyclosporine, etretinate, phototherapy, and a number of biologics including etanercept (Enbrel), alefacept (Amevive), efalizumab (Raptiva), and off-label use of infliximab (Remicaid).

The PASI score

The most popular measure of efficacy in clinical studies (but not clinical practice) is the Psoriasis Area and Severity Index (PASI) score. An improvement in the PASI score of at least 75 percent (called a PASI 75) is considered a reasonable indication of efficacy. There are few head-to-head studies comparing any of the various therapies and certainly no single comprehensive study, but even though the study design and reporting varies, it is safe to say that efficacy rates for improvement for the various systemic and phototherapies range from 20 percent improvement to 80 percent. The latter has been reported as the approximate improvement seen for infliximab and cyclosporine.

The biologics have certainly become popular with patients and physicians for a variety of reasons, not the least of which is their ease of use and relative safety compared to other systemic therapies. But their costs are considerable, ranging from approximately $11,000 to $18,000 per year depending upon drug, dose, and frequency of use. A recent article on the use of home UVB estimated the total cost for 30 years of therapy at about $7,000. For the same time period, biologic therapy cost from $172,000 to $320,000. In real practice, UVB would most likely need to be combined with other agents, particularly

topical steroid agents, for effective, safe and convenient long term therapy for psoriasis with extensive disease.

Clobetasol

Recently, Galderma launched a new formulation of clobetasol as a spray (Clobex). Clobetasol is a super-high-potent topical steroid that has been around for several decades. The new formulation is a patented formulation in a pump spray container. According to the product monograph, clinical studies demonstrated an 82 percent success rate in achieving a "clear" to "almost clear" endpoint in patients with moderate-to-severe psoriasis (meaning patients with psoriasis covering 10–20 percent of their body surface area) over a four-week active therapy period. Four weeks after the treatment, 50 percent of the patients remained clear to almost clear.

Obviously these studies were not done in a head-to-head trial against the biologic therapies, but they appear, at least outwardly, to rival the biologic therapies in patients with similar severity at a small fraction of the cost of a biologic.

These outcomes are also much better than older formulations of clobetasol for reasons that remain unknown. The manufacturer suggests that the alcohol vehicle, combined with an emollient to prevent drying of the skin from the alcohol, works better than the old creams. Alcohol carries the active ingredient deeper into the skin than creams do.

Busy schedules prevent the frequent trips to the dermatologists and benefit designs discourage chronic use of both home and office-based UV therapy. Home UVB solves this.

Of course, as the saying goes, you don't get something for nothing. The product has been shown to produce hypothalamic-pituitary-adrenal (HSA) axis suppression. HPA axis suppression is a well-known side effect of all super-potent steroids and there does not appear to be a higher risk of this side effect with Clobex spray than with other products in this class.

This effect was transitory in the phase 2 studies with all patients returning to normal function within 16 days of discontinuing therapy. But this side effect obviously limits long term exposure to high potency topical steroids. Thus, another therapy would probably be needed in clinical practice.

Ultraviolet therapy

Ultraviolet light is also an old therapy for psoriasis. There are basically two types of UV therapy, UVA and UVB. Dermatologists have used combinations of psoralen (a light-activated agent) along with UVA (termed PUVA) in their offices for years with excellent results. In addition home, UVB light boxes have been around for years. But there has been a long term fear of increased skin cancer from any form of UV light. These fears have been somewhat displaced after the publication of two different studies that demonstrated no increased risk in cancer with long term use of UV light for psoriasis. In fact, one study looked at the worldwide literature and found no evidence of increased risk.

One of the major problems with light therapy has been the time for therapy. Light applications must be applied several times per week. Busy schedules prevent the frequent trips to the dermatologists and benefit designs discourage chronic use of both home and office-based UV therapy. Home UVB solves this.

Narrow-band UVB

Improvements in the home UVB therapies occurred with the introduction of narrow-band (wavelengths of 311–313 nm). Narrow-band UVB is safer than broad band and requires just a few minutes per week for effective outcomes. Home UVB units can be purchased with a doctor's prescription for about $2,300.

The hardware will last about 30 years with normal home use. The light bulbs will need to be replaced about every 5 to 10 years. Typically, patients start with 80 seconds of application time and progress to about 4–8 minutes three times per week. This results in nearly 80 percent of patients achieving PASI 75.

The new units also have built-in safety modules that shut the unit down after specified periods of time until a dermatologist gives a special code to reactivate the unit, thus ensuring proper follow-up with the professionals. Interestingly, only about 1 in 3 patients has ever tried UV therapy.

It appears that a combination of both home UVB along with the topical application of Clobex spray with other topicals such as calcipotriene offers a long-term solution to the high cost of the biologics.

Managed care has barriers in place that prevent patients from accessing these therapies. Complicated prior-authorization processes, high copayments for office-based UV therapy, durable medical equipment copayments, and high DME deductibles all make UV therapy difficult to obtain, leading Steven R. Feldman, MD, to comment in *Dermatology Times*, "Psoriasis patients in some plans have a copayment in each phototherapy visit.... This encourages patients to get a $20,000-a-year biologic rather than phototherapy which, from a global perspective, should be the first-line treatment."

How should plans react?

In the past, I have strongly suggested in this column that MCOs utilize an integrated pharmacy-medical management approach. With this disease, I suggest an even more complicated integration with the addition of the DME benefit to the coverage policies and processes.

It appears intuitive that by utilizing a stepped-care approach that facilitates the access to UVB by reducing or eliminating the DME deductible, and by allowing access to newer formulations of older technologies, lower total costs can be achieved. In addition, safety concerns appear to be minimal due to the lack of evidence of long term damage, safety cut-off modules, and the ensured professional follow-up, combined with intermittent high-potency topical steroid use that minimizes the steroid risks.

Finally, as our society moves toward a high-deductible, cost-sharing approach to medical finance, this opportunity allows patients to afford both their psoriasis treatment their house! MC