STUDY

Recent Trends in Systemic Psoriasis Treatment Costs

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Objectives: To analyze the current total cost of systemic therapy for psoriasis and to compare annual trends in the cost of both generic and brand-name therapies with trends in the Consumer Price Index–Urban since 2000.

Design: A cost model was developed that includes costs for prescription drugs, office visits, and suggested laboratory tests and monitoring procedures. Annual trends in psoriasis drug costs from 2000 through 2008 were analyzed by calculating the percentage change in the average wholesale price from the previous year; these values were compared with changes in the yearly Consumer Price Index–Urban values.

Setting: The United States.

Main Outcome Measures: Total annual costs for systemic psoriasis therapies and trends in cost compared with the trends in Consumer Price Index–Urban values (equivalent to inflation).

Results: Current total annual costs for systemic psoriasis therapies ranged from $1197 (methotrexate) to $27 577 (alefacept, two 12-week courses). Trends in the average wholesale price of brand-name psoriasis therapies from 2000 through 2008 demonstrate an average increase of 66% (range, –24% to +316%); thus, costs of several brand-name psoriasis drugs greatly outpaced the rates of inflation for all items and all prescription drugs.

Conclusions: Despite the higher monitoring costs associated with traditional systemic therapies, annual costs of biologics exceed those of other available therapies. Current trends demonstrate that systemic psoriasis therapy costs are increasing at a much higher rate compared with general inflation.

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PSORIASIS IS A CHRONIC AUTOIMmune disease that affects 1% to 3% of the general population and involves an estimated 4.5 million to 7.5 million Americans.[1] The severity of psoriasis varies significantly, with disease ranging from scattered papules to generalized scaly plaques.[2] The effect of the disease on the quality of life or physical and emotional well-being of a patient differs for each patient and often relates to the extent and location of the lesions.[2,3] Therapeutic options for psoriasis are also varied: they consist of topical agents, phototherapy, and systemic therapies, such as retinoids, cyclosporine, methotrexate, and the 5 biologic agents that are currently approved by the Food and Drug Administration (FDA) for psoriasis and/or psoriatic arthritis. Published consensus guidelines recommend topical therapies for patients with mild, localized disease that does not interfere with activities of daily living, whereas phototherapy and systemic therapies are used for more extensive disease.[4]

Up to one-third of Americans with psoriasis have moderate to severe disease that cannot be controlled with topical treatments alone.[5] Despite the increased efficacy of systemic therapies relative to topical treatments in moderate to severe disease, these therapies appear to be underused. Studies[6] have demonstrated that only 43% of patients with severe psoriasis are receiving systemic therapy of any kind. Reluctance by physicians to prescribe systemic therapies or by patients to adhere to systemic treatment regimens may be owing to several factors, such as intolerance of treatment, adverse effects, patient affordability, and fear of potential adverse effects.[7,8] The issue of affordability is especially relevant, with changing insurance plans, rising copayments, and current trends in prescription drug prices increasing the cost burden of psoriasis. Newer, more expensive biologic therapies have increased the awareness of the cost of psoriasis therapy.[9] Despite their significant impact on disease control and quality of life in patients with psoriasis, the high cost of biologic therapies relative to more traditional systemic therapies requires careful decision making when choosing among the therapeutic options discussed in this article.

Analysis of treatment cost is especially important with regard to a chronic disease such as psoriasis, which often requires lifelong management. The heavy economic burden of psoriasis has been estimated to exceed $3 billion to the health care industry annually.[10] Previous estimates of the direct cost of pso-

riasis, including drugs and hospitalizations, have demonstrated total costs of $649.6 million for 1.4 million patients with psoriasis in 1997.[11] However, recent approval of costly biologic therapies and changing health care costs call for updated cost analyses. In addition, awareness of current trends in prescription drug costs, which demonstrate that increasing prescription drug costs have outpaced Consumer Price Index–Urban (CPI-U) rates, which are generally considered synonymous with the rate of inflation,[12] is also essential when making therapeutic decisions. We hypothesized that this current trend also applies to the cost of prescription medications for the treatment of psoriasis. This study compares the current cost of treatment among different systemic psoriasis therapies and compares recent trends in psoriasis drug costs to trends in general CPI-U rates and all prescription drug costs. Findings from this study will help physicians and employers understand the current costs and trends associated with psoriasis treatment.

METHODS

A cost model based on continuous, year-long treatment was developed for each therapy, which includes costs of medications, office visits, laboratory tests, and monitoring procedures. The cost model was based on clinical experience and published and manufacturer's guidelines.[13-15] Specifically, costs for alefacept (Amevive; Biogen Idec, Cambridge, Massachusetts) were based on two 12-week treatment courses per year or one 16-week treatment course.[16] Despite its withdrawal from the US market in 2009, we included data with regard to efalizumab for the sake of comparison with other available therapies in the analyzed period. Costs for UV-B and psoralen–UV-A (PUVA) therapy were based on a total of 42 treatments per year, with 12 weeks of thrice-weekly induction treatments and maintenance therapy of 2 treatments per month for 9 months per year. Costs for the first year of treatment with adalimumab include a 80-mg loading dose at week 1, followed by 40 mg at week 2, followed by 40 mg every other week. Estimates of cost for the first year of treatment for etanercept include a loading dose of 50 mg subcutaneously twice weekly for 12 weeks followed by 50 mg subcutaneously weekly. Costs for the first year of infliximab therapy include a dose of 5 mg/kg at weeks 0, 2, and 6 and then every 8 weeks. Because of the variability in guidelines for laboratory monitoring during treatment with biologic therapies, the cost model includes only those monitoring tests recommended by the FDA.

Costs for each therapy were assessed from the perspective of the third-party payer by use of the average wholesale price (AWP) of each drug.[17] When calculating medication costs, we assumed a patient weight of 80 kg and, in the case of the biologics efalizumab and infliximab, assumed that vials of medication were fully used during treatment. Costs for infliximab were based on a 3-hour infusion time. Monitoring costs for methotrexate include a liver biopsy (*Current Procedural Terminology* [*CPT*][18] code 47000) to factor in the highest potential cost for this drug therapy (even though the liver biopsy would be performed less than yearly).

Costs of outpatient office visits, laboratory testing, infusions, and other suggested laboratory and related monitoring procedures were determined by means of the 2008 Medicare National Median Physician Reimbursement schedule and Clinical Laboratory Fee schedule (**Table 1** and **Table 2**).[19] Under the assumption that most patients with psoriasis are established patients, the costs of office visits were calculated in the same manner as level 3 return visits. We used *CPT* codes to search for costs of laboratory tests and procedures.[20] All costs were calculated in US dollars. Additional direct costs, such as hospitalizations or costs associated with medication adverse effects, and indirect costs, such as time away from work, were not included in this analysis.

Table 1. Laboratory and Procedure Costs in US Dollars

Item/*CPT* Code[a]	Medicare Reimbursement, US $
Level 3 established patient/99213	65.33
Eye examination/92012	76.56
Fundus photographs/92250	75.73
Liver biopsy/47000	297.93
Intravenous infusion up to 1 hour/90765	80.72
Intravenous infusion, per additional hour/90766	25.80
UV-B therapy/96910	64.08
PUVA therapy/96912	81.97
Chest x-ray examination/71020	36.20
PPD/86580	9.15
Absolute CD4/CD8 cell count/86360	88.71
CBC with differential/85025	14.68
Triglycerides/84478	10.86
Cholesterol/82465	8.22
Lipid panel[b]/80061	18.72
Creatinine/82565	9.67
Urea nitrogen/84520	7.45
Uric acid/84550	8.53
Magnesium/83735	12.65
Potassium/84132	8.67
BMP/80048	15.98
CMP/80053	19.96
SGOT/84450	9.76
SGPT/84460	10.00
Hepatic function panel/80 076	15.43

Abbreviations: BMP, basic metabolic panel; CBC, complete blood cell count; CMP, comprehensive metabolic panel; *CPT*, *Current Procedural Terminology*; PPD, purified protein derivative (tuberculin); PUVA, psoralen–UV-A; SGOT, serum glutamic oxaloacetic transaminase; SGPT, serum glutamic pyruvic transaminase.

[a] From the American Medical Association Web site (laboratory values for the midpoint of 2007).[18]

[b] Lipid panel includes high-density lipoprotein cholesterol, total serum cholesterol, total lipoprotein cholesterol, triglycerides, and low-density lipoprotein cholesterol calculation.

Annual trends in psoriasis drug costs from 2000 until 2008 were analyzed by calculating the percentage change in AWP from the previous year. In addition, total percentage change from 2000 to 2008 was calculated by means of the following formula: 100 (AWP [2000] – AWP [2008])/AWP (2000). Changes in CPI-U rates for all items and for prescription drugs were determined by the use of CPI values for all urban consumers (US city average) because these values are generally considered equivalent to the rate of inflation.[21] Therefore, any discussion of trends in inflation rates in this study is solely based on CPI-U values.

RESULTS

Our analyses were developed to answer 2 questions. First, what is the current, direct cost of systemic therapy for psoriasis? Second, what is the trend in these costs relative to general inflation?

COST OF PSORIASIS TREATMENT

To assess costs for psoriasis therapy, we used a cost model to compare the direct annual costs of phototherapy, systemic agents, and biologics (Tables 1 and 2). Results of our cost analysis are summarized in **Table 3**. The

Table 2. Annual Monitoring Guidelines for All Drugs Discussed

Therapy	Laboratory Testing and Specialty Examinations	Frequency of Office Visits, Return Level 3
UV-B phototherapy	None	Monthly during induction phase (3 mo), then every 3 mo during maintenance
PUVA	Twice-yearly eye examinations, yearly fundus photographs	Same as UV-B
Acitretin	Measurement of triglycerides, cholesterol, SGOT (AST), SGPT (ALT), and CBC monthly for 3 mo, then once every 3 mo	Monthly initially (3 mo), then every 3 mo for 6 visits annually
Methotrexate	Measurement of CBC, SGOT, and SGPT initially every 2 wk for 2 mo, eventually every 2 mo, 1 liver biopsy	Monthly initially (3 mo), then every 3 mo for 6 visits annually
Cyclosporine	Measurement of CMP (initiation of therapy), BUN, creatinine, triglycerides, cholesterol, SGOT, SGPT, uric acid, potassium, and magnesium initially every 2 wk for 1-2 mo, then every other month	Every 2 wk for 1-2 mo, then every 2 mo for 7 visits annually
Adalimumab	Yearly PPD test	4 Visits yearly
Alefacept	CD4/CD8 cell counts weekly during treatment (24 CD4/CD8 cell counts for 2 courses of 12 wk, 16 counts for 16-wk course)	24 Visits for 2 courses of 12 wk, 16 visits for 16-wk course
Efalizumab[a]	Initially monthly CBCs for 3 mo, then every 3 mo (6 total CBCs)	4 Visits yearly
Etanercept	Yearly PPD skin test	4 Visits yearly
Infliximab	Yearly PPD skin test	4 Visits yearly

Abbreviations: ALT, alanine aminotransferase; AST, aspartate aminotransferase; BUN, blood urea nitrogen; CBC, complete blood cell count; CMP, comprehensive metabolic panel; PPD, purified protein derivative (tuberculin); PUVA, psoralen–UV-A; SGOT, serum glutamic oxaloacetic transaminase; SGPT, serum glutamic pyruvic transaminase.

[a]This drug was withdrawn from the US market in April 2009. However, since this study is an analysis of psoriasis drug costs from 2000 to 2008, data with regard to efalizumab were included for the sake of comparison to other therapies.

Table 3. Comparison of Annual Costs for Psoriasis Phototherapy and Systemic Therapy

Therapy	Dose and Frequency	Medication Cost (AWP),[a] $	Phototherapy Cost, $	Monitoring Cost, $	Office Visit Cost, $	Total Annual Cost, $
UV-B phototherapy, induction	Twice weekly for 3 mo		1538		196	1734
UV-B phototherapy, maintenance	Twice monthly		1153		261	1414
PUVA phototherapy (with methoxsalen [Oxsoralen-Ultra])	30 mg twice weekly for 3 mo	1843	1967	229	196	4235
PUVA phototherapy, maintenance	Twice monthly	1382	1475	229	261	3347
Acitretin						
	25 mg/d	8450		321	392	9163
	50 mg/d	16 900		321	392	17 613
Methotrexate[b]						
	7.5 mg/wk	197		608	392	1197
	15 mg/wk	393		608	392	1393
Cyclosporine[c] (Neoral)						
	300 mg/d	6690		621	457	7768
	400 mg/d	8921		621	457	9999
Adalimumab						
Year 1[d]	Includes 80-mg loading dose	23 267		10	261	23 538
Year 2	40 mg subcutaneously every other week	21 605		10	261	21 876
Alefacept						
	Two 12-wk courses, 15 mg intramuscularly per week	23 880		2129	1568	27 577
	One 16-wk course	15 920		1419	1045	18 384
Efalizumab[e]	1 mg/kg subcutaneously weekly	24 090		88	261	24 439
Etanercept						
Year 1[f]	Includes loading dose	26 591		10	261	26 862
Year 2	50 mg subcutaneously weekly	21 605		10	261	21 876
Infliximab						
Year 1[g]	5 mg/kg intravenously, 400 mg maximum daily	22 308		1070	261	23 639
Year 2	5 mg/kg intravenously, 400 mg maximum daily	19 520		936	261	20 717

Abbreviations: AWP, average wholesale price; PUVA, psoralen–UV-A.

[a]All costs based on brand-name AWP for 2008; costs in US dollars.

[b]Monitoring cost includes 1 liver biopsy.

[c]Comprehensive metabolic panel performed on initiation of therapy.

[d]Adalimumab year 1: regimen of 80 mg at week 1, 40 mg at week 2, 0 mg at week 3, then 40 mg every other week.

[e]This drug was withdrawn from the US market in April 2009. However, since this study is an analysis of psoriasis drug costs from 2000 to 2008, data with regard to efalizumab were included for the sake of comparison to other therapies.

[f]Etanercept year 1: loading dose of 50 mg subcutaneously twice weekly for 12 weeks, followed by 50 mg weekly.

[g]Infliximab year 1: loading dose of 5 mg/kg at weeks 0, 2, and 6 and then every 8 weeks (year 1: 8 total infusions, year 2: 7 infusions). Monitoring costs include 1 purified protein derivative (tuberculin) and infusion costs ($132.32 for 3 hours). The 400-mg dose is based on a patient weight of 80 kg.

Table 4. Psoriasis Systemic Therapy AWP Trends (Price per Dose)

Generic Name (Trade Name), Dose	AWP, $[a] 2000	2001	2002	2003	2004	2005	2006	2007	2008	Percentage Change[b]/ CPI-U Percentage Change (Years Analyzed)[c]
Methoxsalen (Oxsoralen-Ultra), 10 mg	6.16	6.16 (0)	6.77 (9.9)	6.77 (0)	7.79 (15.1)	12.97 (66.5)	22.17 (70.9)	22.17 (0)	25.61 (15.5)	315.7/25.8 (9)
Acitretin (Soriatane), 25 mg	8.99	11.71 (30.3)	12.29 (5.0)	13.55 (10.3)	14.91 (10)	17.70 (18.7)	18.72 (5.8)	21.84 (16.7)	23.15 (6.0)	157.5/25.8 (9)
Methotrexate (Trexall),[d] 2.5 mg	1.66	1.66 (0)	1.26 (–24)	1.26 (0)	1.26 (0)	1.26 (0)	1.26 (0)	1.26 (0)	1.26 (0)	–24.1/25.8 (9)
Methotrexate (generic),[d,e] 2.5 mg	4.47	4.47 (0)	4.14 (–7.4)	4.39 (6.0)	4.36 (–0.7)	4.36 (0)	4.46 (2.3)	4.56 (2.2)	4.80 (5.3)	7.0/25.8 (9)
Cyclosporine (Neoral),[d] 100 mg	6.11	6.11 (0)	6.11 (0)	6.11 (0)	6.11 (0)	6.11 (0)	6.11 (0)	6.11 (0)	6.11 (0)	0/25.8 (9)
Cyclosporine (Gengraf),[d] 100 mg		5.50	5.50 (0)	5.50 (0)	5.50 (0)	5.50 (0)	5.28 (–4)	5.28 (0)	5.28 (0)	–4.0/23.8 (8)
Adalimumab (Humira), 40 mg				653.30	577.11 (–11.7)	690.15 (19.6)	719.86 (4.3)	755.14 (4.9)	830.96 (10)	27.2/18.7 (6)
Alefacept (Amevive), 15 mg				995.00	995.00 (0)	995.00 (0)	995.00 (0)	995.00 (0)	995.00 (0)	0/18.7 (6)
Efalizumab (Raptiva),[f] 125 mg					343.00	360.15 (5.0)	404.63 (12.4)	432.95 (7.0)	463.26 (7.0)	35.1/15.0 (5)
Etanercept (ENBREL), 25 mg	141.49	148.43 (4.9)	155.70 (4.9)	163.33 (4.9)	164.47 (0.7)	172.54 (4.9)	179.96 (4.3)	188.78 (4.9)	207.74 (10)	46.8./25.8 (9)
Infliximab (Remicade), 100 mg	611.33	665.65 (8.9)	691.61 (3.9)	691.61 (0)	691.61 (0)	691.61 (0)	662.68 (–4.2)	670.96 (1.2)	697.13 (3.9)	14.0/25.8 (9)

Abbreviations: AWP, average wholesale price; CPI-U, Consumer Price Index–Urban.
[a] Numbers in parentheses indicate percentage change in AWP of medication from previous year.
[b] Percentage change calculated from first year of availability until 2008 (for most drugs, calculated change is from 2000 to 2008).
[c] Years analyzed includes number of total years the medication has been approved by the Food and Drug Administration since 2000, with the corresponding CPI increase (all items) during that period.
[d] Prices for methotrexate and cyclosporine based on oral therapy.
[e] Generic cost of methotrexate calculated as average of Trexall and Rheumatrex.
[f] This drug was withdrawn from the US market in April 2009. However, since this study is an analysis of psoriasis drug costs from 2000 to 2008, data with regard to efalizumab were included for the sake of comparison to other therapies.

annual costs ranged from $1197 for methotrexate, 7.5 mg weekly, to $27 577 for two 12-week courses of alefacept. Phototherapy costs ranged from $3083 per year for UV-B therapy to $7288 for PUVA annually (including induction and maintenance costs). Costs for acitretin, 25 mg daily ($9163), were comparable to those for cyclosporine, 400 mg daily ($9999); however, some patients require 50 mg/d of acitretin, which translates to an annual cost of $17 613.

Annual costs of the biologics used for psoriasis therapy ranged from $18 384 to $27 577. The therapies that require loading doses (adalimumab, etanercept, and infliximab) were more costly during the first year of treatment compared with subsequent years ($23 538 vs $21 876 for adalimumab, $26 862 vs $21 876 for etanercept, and $23 639 vs $20 717 for infliximab). Overall, prices for the recommended dosing of the biologics were comparable. However, estimates of total costs of biologic regimens that have been studied in clinical trials[22] but are not the current recommended regimen were found to vary considerably from our cost calculations. For example, patients treated with efalizumab, 2 mg/kg subcutaneously weekly, accumulate an annual cost $48 530, whereas treatment with etanercept, 50 mg, sustained at this dose twice weekly incurs an annual cost of $43 732.

RECENT TRENDS IN TREATMENT COST

We analyzed trends in AWP for the various brand-name and generic systemic psoriasis treatments from 2000 through 2008 (**Table 4**). The percentage changes in drug prices between 2000 and 2008 ranged from –24.1% for methotrexate to +316% for the brand-name version of methoxsalen (Oxsoralen-Ultra; Valeant Pharmaceuticals International, Aliso Viejo, California). Acitretin (Soriatane; Stiefel Laboratories Inc, Coral Gables, Florida) had the second largest increase (157.5%) during this period. Conversely, 1 brand-name version of cyclosporine (Neoral; Novartis Pharmaceuticals Corporation, Basel, Switzerland) did not increase in price during this 8-year

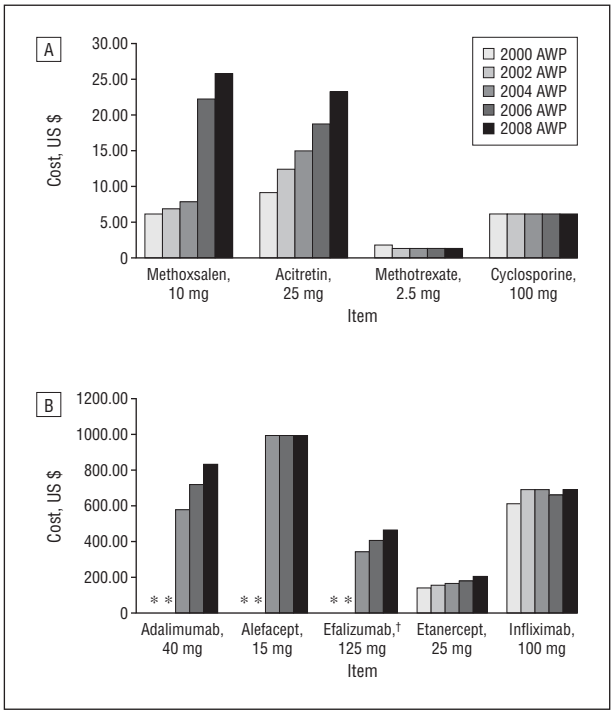

Figure 1. Trends in cost of traditional and biologic psoriasis therapies from 2000 to 2008. A, Traditional therapies. Methoxsalen had the largest percentage increase in drug cost (315.7%), whereas acitretin increased in price by 157.5%. Costs for methotrexate and cyclosporine did not increase. B, Biologic therapies. Efalizumab increased in cost by 35.1% during a 4-year interval, whereas the average wholesale price (AWP) of adalimumab increased by 27.2% from 2003 until 2008. Etanercept increased steadily in cost by 46.8% from 2000 to 2008. *Years when corresponding medications were not yet available. †This drug was withdrawn from the US market in April 2009. However, since this study is an analysis of psoriasis drug costs from 2000 to 2008, data with regard to efalizumab were included for the sake of comparison to other therapies.

interval, whereas another (Gengraf; Abbott Laboratories, Abbott Park, Illinois) decreased in price by 4.0%. When analyzing trends in drug costs for the biologics, the interval must be considered because a few of these therapies have only been available since 2003 or 2004. For example, efalizumab (Raptiva; Genentech Inc, South San Francisco, California) increased in cost by 35.1% during a 4-year interval. Similarly, the AWP of adalimumab (Humira; Abbott Laboratories) increased by 27.2% during a 5-year interval (from 2003 to 2008). Etanercept (ENBREL; Immunex Corporation, Thousand Oaks, California) increased in cost by 46.8% from 2000 to 2008, whereas infliximab increased by only 14.0%, and the cost of alefacept has not changed during the same interval. Annual percentage change in drug prices fluctuate widely (Table 4, **Figure 1**, and **Figure 2**); for example, a significant increase in the cost of the brand-name version of methoxsalen (Oxsoralen-Ultra) was observed between 2004 and 2006 (184.6%). Therapies such as acitretin, adalimumab, efalizumab, and etanercept have increased in cost steadily every year, whereas methotrexate, cyclosporine, and alefacept have seen minor, if any, increases in price since 2000.

To test our hypothesis that psoriasis treatment costs have been increasing at a rate greater than the CPI-U, trends in psoriasis treatment costs from 2000 through 2008 were compared with the CPI-U[21] for all items and all prescription drugs during the same period. There was an increase of 25.8% for all items and a 30.1% increase in prescription drug costs (**Table 5**). The increase in CPI-U values, which is considered equivalent to general inflation, was greatest between 2007 and 2008 (4.2%), whereas prescription drug prices increased by a significant 6.0% between 2000 and 2001. Costs for all psoriasis medications except methotrexate, cyclosporine, alefacept, and infliximab have increased at a substantially greater rate than the CPI-U rate for all items and prescription drugs (Tables 4 and 5, and Figure 2A and B).

COMMENT

DIRECT COST OF PSORIASIS TREATMENT

The results of our cost analysis, summarized in Table 3, revealed that the most costly of the currently recommended treatment regimens is alefacept (two 12-week treatments) at $27 577 per year, whereas the least costly treatment is methotrexate ($1197-$1393 annually, depending on the dose). Published cost-effectiveness analyses have demonstrated annual costs for psoriasis medication of up to $37 000; however, these analyses included costs for treatment regimens that are often prescribed but not currently published as recommended regimens, such as adalimumab, 40 mg weekly, or efalizumab, 2 mg/kg subcutaneously weekly.[9,16] Indeed, using our cost model, we calculated an annual cost of $48 530 for efalizumab, 2 mg/kg subcutaneously weekly.

Our analysis demonstrated a greater annual cost for PUVA therapy ($7288) relative to UV-B therapy ($3083); this is in part owing to the increasing cost of methoxsalen therapy, as well as additional costs associated with required monitoring during PUVA therapy. Thus, our cost estimates for PUVA therapy are substantially greater than those previously published.[23] The results of our cost analysis are similar to previously published cost analyses; discrepancies may be accounted for by the use of different monitoring guidelines and increasing costs of medications, procedures, or clinical laboratory fees. Although various studies[24,25] have recommended laboratory screening and monitoring tests for patients treated with biologic therapies, our cost model included only those guidelines recommended by the FDA. Including additional screening tests would have caused a nominal increase in the annual cost of biologic therapies. Our analysis did not include indirect costs, such as time away from work, direct costs such as hospitalizations, or costs related to adverse effects. In addition, costs were calculated by means of the 2008 Medicare National Median Physician Reimbursement schedule and Clinical Laboratory Fee schedule; retail costs for patients who do not qualify for Medicare may be higher. However, because our cost model analyzes annual costs for therapies, many of which are not given for a full year, the model may overestimate costs of certain drug regimens.

Of note, annual costs were assessed by means of the AWP for each therapy, which may not accurately reflect market prices for medications. The AWP is a reference price reported in publications such as the *Red Book*[17] and

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