



## ORIGINAL ARTICLE

# Importance of out-of-pocket costs for adult patients with atopic dermatitis in France

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## Abstract

**Background** Currently, few studies investigated the economic burden of atopic dermatitis (AD) in adult patients and specifically the estimation of out-of-pocket costs. Patients with skin disorders primarily use comfort care to ease dryness, itch or pain, and the costs of comfort care are not subject to any reimbursement from mandatory or complementary insurance.

**Objective** The purpose of this study was to measure the medical and non-medical expenses paid by the patient.

**Methods** Eczema Cohort Longitudinal Adults was a non-interventional study that aimed to assess the burden of AD in terms of quality of life and financial consequences. A self-assessment questionnaire was distributed to adult patients who were cared in four French hospitals. Patients were asked to list the resources consumed for the treatment of AD during the last 12 months and to estimate the corresponding amount of money they had to pay out of their own pockets. The severity of AD was subjected to a stratification based on the PO-SCORAD score.

**Results** A total of 1024 patients answered the questionnaire: 31.9% with severe AD, 40.4% with moderate AD and 27.6% with mild AD. The mean annual out-of-pocket cost was €462.1 for severe AD and €247.4 for moderate AD. Emollients were the most commonly used product: 74.4% for an average out-of-pocket cost of €151.4. The out-of-pocket costs increased significantly with the severity: 27% of patients with severe AD declared having bought specially textured clothes, while 19% of patients with moderate AD reported the same. The corresponding mean out-of-pocket costs were €162 and €91, respectively.

**Conclusion** The amount of out-of-pocket costs for patients with AD for essential medical and non-medical expenses is relatively high, compared to the average out-of-pocket cost for French households. Integration of these essential resources into the list of reimbursed products and services appears necessary for a better coverage of AD.

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## Conflicts of interest

RL, EC and CT: employee of REES France; LM: Beiersdorf, Bioderma, Expanscience, Galderma, Johnson&Johnson, Leo Pharma, Novartis, Pierre Fabre, Roche-Posay, Sanofi, Uriage; KE, SM and SH: none; Z and JS: Sanofi.

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## Introduction

Atopic dermatitis (AD) is a chronic relapsing inflammatory skin disease primarily affecting children. The usual onset of the disease is between 3 and 6 months after birth. The prevalence of AD has significantly increased over the past years, affecting approximately one infant out of 10. According to a French study, the prevalence of AD for patients over 15 is 4.65% (4652 patients per 100 000 people in France) and women are twice as affected as men.<sup>1</sup> The most recent studies indicate the disorder's prevalence increases in industrialized nations, while it remains low in developing ones.<sup>2</sup> The incidence and severity of AD decrease with patient age. Most patients become clear of AD at childhood (50% before age 5). However, in the last decade, much attention has been paid to AD persisting or appearing in adulthood, and 10–15% of patients affected during infancy continue to suffer from AD in adulthood.<sup>3</sup>

Although this disorder is not deadly, its clinical manifestations are in most cases, very disabling. The unpredictable occurrence of eczema lesions makes this condition uncomfortable and very visible. Its impact affects people's morale, sleep, quality of life and day-to-day activities. In the United States, AD was associated with higher rates of anxiety, depression, lost productivity, activity impairment and poorer health-related quality of life compared with patients without AD.<sup>4,5</sup> In France, an altered quality of life was found in patients who had visible areas involvement.<sup>6</sup> Moreover, the same study showed AD had an impact on patients' sexual health by affecting their sexual desire.

In addition, no one can neglect the financial consequences it entails on household budgets. The literature reports elevated costs of AD in the United States, for both the payer and the patient.<sup>7,8</sup> In a nation with a high level of social protection like France, it must be noted that the expenses linked to dermatitis care are not included in the products and services covered by the national health insurance, and this introduces an out-of-pocket cost to families.<sup>9</sup> Indeed, patients with AD or skin disorders primarily use comfort care to ease dryness, itch or pain, and the costs of comfort care are not subject to any reimbursement from mandatory or complementary insurance.

In France, the current health expenditures (*Dépenses courantes de santé*) are funded by several organizations: statutory and voluntary health insurance, state and local communities and households. Interventions by these actors do not cover the same expense categories. The state is the main payer for prevention, medical education, medical research and the care provided to the most deprived patients. Mandatory health insurance, complementary voluntary health insurance and the insured themselves (household) provide the funding for hospitalization, outpatient care and medical products (*Consommation de soins et de biens médicaux*) as soon as the corresponding goods and services are qualified as medical costs by the sickness fund. A general principle of financial coverage by statutory health

insurance is the partial reimbursement, meaning the health insurance fund retains a proportion of the total cost of treatment. The fraction of the health expenditures to be paid by the households once mandatory health insurance has reimbursed its share is called 'ticket modérateur' and is equivalent to a statutory coinsurance (a percentage of charge that the consumer must pay). The patient's contribution to the total cost of treatment varies according to the type of treatment and is higher for outpatient care and drugs than for hospital treatment. On average, the total reimbursements paid by the statutory health insurance are equal to 75% of the qualified expenditures. In certain circumstances, patients are exempt from these coinsurance expenses, and their health insurance fund then covers the total cost of treatment, in particular, when the person insured is suffering from one of the 30 specified long-term illnesses (such as diabetes, AIDS, cancer or psychiatric illness). In general, private health insurance, which in France is supplementary rather than an alternative to the statutory health insurance, covers the coinsurance partially or totally according to the type of contract subscribed. Finally, the 'direct' patient contribution to the total cost of treatment is equal to the value of the coinsurance not reimbursed by the complementary voluntary health insurance plus the expenses not considered by the sickness funds as a medical cost, such as the physician's charges in excess of the official payment amount or hygiene products.

Currently, few studies have been conducted to estimate the economic burden of AD in adult patients and specifically to the estimation of out-of-pocket costs for patients. A French study estimated the cost of AD in children and showed higher treatment rates and higher costs for the affected infants compared to non-affected infants of the same age.<sup>10</sup> The purpose of our study was to measure the medical and non-medical expenses not covered by public or private health insurers and instead paid by the adult patient as an out-of-pocket cost in France. To our knowledge, this is the first undertaken in this area in Europe.

## Patients and methods

### Study design

The Eczema Cohort Longitudinal Adults (ECLA) study was a non-interventional and multicentric study conducted in France. Our study is a baseline analysis of ECLA. A self-assessment questionnaire developed by members of the study's scientific committee who are specialists in the field was proposed by dermatologists to all adult patients diagnosed with AD attending one of the four dermatology wards participating in the study. They were evenly distributed across the country (Brest, Bordeaux, Créteil or Reims) and represented every type of facility care (public and ambulatory consultation). In addition, the questionnaire was sent to members of the French Eczema Patient Association. Some of them were active members, and others

could be included if they have just asked a question to the association in the past.

The aim of this questionnaire was to bring data about demographics, patient care, history of the disease, care pathway, affected areas, out-of-pocket cost, and impact on sexuality, work, spouse and family environment. It came along with four other validated questionnaires: the SF-12 health survey (12-Item Short-Form), a shorter form of the SF-36, and the EQ-5D, which are not specific to dermatology<sup>11,12</sup>; the Dermatology Life Quality Index, a dermatology-specific questionnaire which aims to assess the consequences of the disease and its treatment on patients' quality of life<sup>13</sup>; and the Atopy Burden Score-Adult which is specific to the burden of AD.<sup>14</sup> Patients who did not understand French, the language of the questionnaires, were excluded from the study. The main objective of this work was to estimate the economic burden of illness depending on its severity stage for patients suffering from AD.

The severity of the AD was stratified with the PO-SCORAD scale. This patient-oriented self-assessment scale has been validated in Europe.<sup>15</sup> It has three dimensions that describe the affected zones and objective and subjective symptoms of the disease. The severity of the AD was described as mild when the score was  $\leq 25$ , moderate if the score was between 25 and 50 and severe when the score was  $\geq 50$ .<sup>16</sup>

### Cost assessment

To estimate the cost of care for patients suffering from AD, the questionnaire asked about utilization in the past 12 months and whether the resource utilization was covered by public or private insurers; the resources that were listed on the questionnaire

included clothing, dressing and bandages, emollients, hygiene products, sun protection and food supplements. Even though all of these resources were not recommended in the management of AD, the study also aimed to describe patients' therapeutic behaviour and to identify the use of complementary therapies.

For each item, the patient was asked to indicate his/her needs, as part of the care of AD, during the past 12 months in terms of resources used and to estimate the corresponding out-of-pocket expenditures for each item. The patient was asked to also estimate the fraction of the overall annual cost of out-of-pocket expenditures linked to AD. This annual out-of-pocket cost was also calculated 'bottom up' by adding the annual expenditure amount not reimbursed under each identified budgetary item. These two out-of-pocket costs – estimated and calculated – were compared to verify the coherence of the results using one or the other approach. Whatever the method implemented, it has been shown in the literature that patients tend to underestimate their health expenditure.<sup>17,18</sup>

### Statistical analysis

The out-of-pocket expenses were stratified according to the severity of the disease and compared between groups. Mean out-of-pocket expenses and their standard deviations were calculated for each group (severe vs. not severe). Median of continuous variables were also displayed to represent the heterogeneity of the variable distributions. Comparisons of frequencies and means between the severity groups were conducted using the chi-square test for categorical variables and, in the absence of normality and homoscedasticity, the Kruskal–Wallis test for continuous variables with a confidence interval level of 95%.

**Table 1** Socio-demographic characteristics of the atopic dermatitis (AD) population

		Mild AD (N = 283)	Moderate AD (N = 414)	Severe AD (N = 327)	P-value	Total (N = 1024)
<b>Sex</b>	Missing	0	0	1	0.0201	1
	Male	135 (47.7%)	173 (41.8%)	119 (36.5%)		427 (41.7%)
	Female	148 (52.3%)	241 (52.3%)	207 (63.5%)		596 (58.3%)
<b>Age</b>	Missing	2	3	4	<0.0001	9
	Mean ( $\pm$ SD)	50.0 ( $\pm$ 13.9)	41.1 ( $\pm$ 14.8)	38.5 ( $\pm$ 14.6)		42.7 ( $\pm$ 15.2)
	Median	50.0	38.0	35.0		40.0
	Min–Max	19.0–83.0	16.0–80.0	16.0–83.0		16.0–83.0
<b>Profession</b>	Missing	1	0	1	<0.0001	2
	Active	167 (59.2%)	289 (69.8%)	235 (72.1%)		691 (67.6%)
	No occupation	32 (11.3%)	31 (7.5%)	29 (8.9%)		92 (9%)
	Retired	76 (27%)	58 (14%)	31 (9.5%)		165 (16.1%)
	Student	7 (2.5%)	36 (8.7%)	31 (9.5%)		74 (7.2%)
<b>Annual revenue</b>	Missing	0	3	3	0.1245	6
	Less than €12 000/year	34 (12%)	52 (12.7%)	45 (13.9%)		131 (12.9%)
	Between 12 000 and €20 000/year	59 (20.8%)	79 (19.2%)	93 (28.7%)		231 (22.7%)
	Between 20 000 and €30 000/year	82 (29%)	111 (27%)	77 (23.8%)		270 (26.5%)
	Between 30 000 and €50 000/year	79 (27.9%)	122 (29.7%)	77 (23.8%)		278 (27.3%)
	More than €50 000/year	29 (10.2%)	47 (11.4%)	32 (9.9%)		108 (10.6%)

## Results

### Socio-demographic characteristics of the population

A total of 1024 subjects answered the questionnaire, of whom 596 (58.3%) were women. After evaluation of the severity of their AD through the PO-SCORAD questionnaire, the subjects were stratified according to their score. A total of 327 patients (31.9%) suffered from severe AD, 414 (40.4%) showed moderate AD, and 283 patients (27.6%) were mildly affected (Table 1).

The sample's median age was 40 years old. A significant difference in age was observed between the three severity groups ( $P < 0.0001$ ). In accordance with the literature, patients with severe AD were younger:  $38.5 \pm 14.6$  years old for the patients affected by severe dermatitis,  $41.1 \pm 14.8$  years for patients with moderate dermatitis and  $50 \pm 13.9$  years for mild dermatitis. The working population comprised 67.6% of the studied population. Employed subjects were more numerous within severely affected patients (72.1% for severe patients, 69.8% for moderate stages and 59.2% for mild stages;  $P < 0.0001$ ). No significant difference was found between severity groups regarding annual income.

### Costs of AD

The total of non-reimbursed expenditures, as estimated by the patients, amounted to an average €350.5 per patient per year [95% CI (€311.4; €389.5)]. The range varied from €0.0 to €4000. This amount increased logically based on the disease's severity: €76.7 [95% CI (€41.4; €111.8)] for mild stages, €247.4 [95% CI (€206.7; €288.1)] for moderate stages and €462.1 [95% CI (€398.9; €525.2)] for severe cases (Table 2). The observed difference between the three severity groups was statistically significant ( $P < 0.0001$ ).

Table 2 also presents the total annual costs spent and not reimbursed as calculated by summing the different consumption estimated by the patient for each expenses item they had to document. The aggregated amount was an increasing function of the degree of severity: €51.7 [95% CI (€40; €63.4)] for mild AD, €197.6 [95% CI (€171.9; €223.4)] for moderate AD and €489.8 [95% CI (€340.8; €638.7)] for severe AD. Once again, the differences between severity groups were significant ( $P < 0.0001$ ).

### Resources utilization and cost of the different budgetary items

The medical and non-medical resources most frequently used by the patients were emollients, hygiene products and sun protection (Fig. 1). The use of an emollient during the past 12 months was declared by 93% of patients affected by severe AD; 82.5% of patients with moderate AD relied on emollients as well as 40.9% of patients with mild AD. The difference in resources utilization for emollients between the different severity groups was statistically significant ( $P < 0.0001$ ). The mean amount of out-of-pocket costs associated with this resource utilization was equal to €254.7 [95% CI (€100.7; €408.7)] for patients with severe AD, €93 [95% CI (€81.3; €104.7)] for moderate AD and €51.5 [95% CI (€39.9; €63.1)] for mild AD (Table 3).

Hygiene products were used in the past 12 months by 85.33% of patients suffering from severe AD, 70.9% of patients with moderate AD and 33.7% of patients affected by mild AD. The amount of out-of-pocket costs estimated by the patients under this item amounted to €103.4, €63.9 and €44.2 per year and per patient for severe, moderate and mild AD, respectively.

The use of specific clothing items was mentioned by less than a fourth of respondents: 26.9% of severe patients, 19.2% of moderate patients and 2.8% of mild AD. However, the out-of-pocket costs associated with this item remained high: €162, €91.1 and €43.6 for severe, moderate and mild AD, respectively. Likewise, the consumption of food supplements was declared by only 18.5% of patients, but still constituted a high out-of-pocket cost at €106.9 on average between all severity groups. Sun protection was used by 38% of patients, and the patients estimate their out-of-pocket cost to an average of €44.8.

21.1% of patients declared having been fully reimbursed by the public health insurance or another supplementary organization for the totality of medical and non-medical expenses they had incurred to treat AD. The proportion of affected reimbursements decreased with severity, reaching 32.4% of incurred expenditures for mild AD, 20.1% for moderate AD and 12.6% for severe AD ( $P < 0.0001$ ).

**Table 2** Total annual out-of-pocket costs estimated or calculated (€)

		Mild AD (N = 283)	Moderate AD (N = 414)	Severe AD (N = 327)	P-value	Total (N = 1024)
Estimated total annual out-of-pocket costs (€)	Missing	255	236	94	<0.0001	585
	Mean ( $\pm$ SD)	76.6 ( $\pm$ 90.7)	247.4 ( $\pm$ 275.1)	462.1 ( $\pm$ 489.4)		350.5 ( $\pm$ 416.7)
	Median	50.0	150.0	300.0		200.0
	Min–Max	0.0–390.0	0.0–1400.0	0.0–4000.0		0.0–4000.0
Calculated total annual out-of-pocket costs (€)	Missing	0	0	0	<0.0001	0
	Mean ( $\pm$ SD)	51.7 ( $\pm$ 100.0)	197.6 ( $\pm$ 266.7)	489.8 ( $\pm$ 1369.2)		250.6 ( $\pm$ 812.0)
	Median	6.0	110.0	290.0		110.0
	Min–Max	0.0–800.0	0.0–2400.0	0.0–23652		0.0–23652

AD, atopic dermatitis.

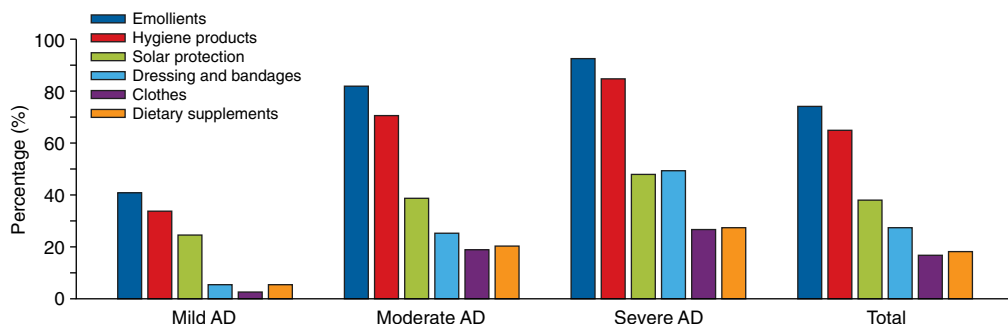


Figure 1 Percentage of needs for each item and severity of atopic dermatitis.

Table 3 Annual out-of-pocket costs estimated (€) for each item

		Mild AD (N = 283)	Moderate AD (N = 414)	Severe AD (N = 327)	P-value	Total (N = 1024)
<b>Emollients</b>	Missing	2	3	0	<0.0001	5
	Need	115 (40.9%)	339 (82.5%)	304 (93%)		758 (74.4%)
	Mean (±SD)	51.5 (±62.9)	93.0 (±109.4)	254.7 (±1357.8)	<0.0001	151.4 (±865.9)
	Median	30.0	50.0	120.0		65.0
	Min–Max	0.0–400.0	0.0–800.0	0.0–23345		0.0–23345
<b>Hygiene products</b>	Missing	1	2	0	<0.0001	3
	Need	95 (33.7%)	292 (70.9%)	279 (85.3%)		666 (65.2%)
	Mean (±SD)	44.2 (±61.9)	63.9 (±77.8)	103.4 (±113.2)	<0.0001	77.6 (±95.1)
	Median	30.0	40.0	70.0		50.0
	Min–Max	0.0–500.0	0.0–700.0	0.0–1000.0		0.0–1000.0
<b>Solar protection</b>	Missing	1	2	0	<0.0001	3
	Need	70 (24.8%)	161 (39.1%)	157 (48%)		388 (38%)
	Mean (±SD)	36.0 (±42.4)	39.1 (±54.9)	54.7 (±63.7)	<0.0001	44.8 (±57.2)
	Median	25.0	25.0	40.0		30.0
	Min–Max	0.0–300.0	0.0–520.0	0.0–500.0		0.0–520.0
<b>Dressing and bandages</b>	Missing	1	2	0	<0.0001	3
	Need	15 (5.3%)	104 (25.2%)	163 (49.8%)		282 (27.6%)
	Mean (±SD)	38.0 (±37.6)	55.0 (±92.2)	86.2 (±96.8)	<0.0001	72.3 (±94.2)
	Median	20.0	30.0	62.5		50.0
	Min–Max	5.0–120.0	0.0–780.0	0.0–1000.0		0.0–1000.0
<b>Clothes</b>	Missing	1	2	0	<0.0001	3
	Need	8 (2.8%)	79 (19.2%)	88 (26.9%)		175 (17.1%)
	Mean (±SD)	43.6 (±42.9)	91.1 (±111.2)	162 (±197.5)	0.0006	125.1 (±163.5)
	Median	30.0	50.0	100.0		65.0
	Min–Max	0.0–100.0	0.0–500.0	0.0–1500.0		0.0–1500.0
<b>Dietary supplements</b>	Missing	1	2	0	<0.0001	3
	Need	15 (5.3%)	85 (20.6%)	89 (27.2%)		189 (18.5%)
	Mean (±SD)	48.2 (±36.8)	88.0 (±144.2)	134.9 (±237.8)	0.0107	106.9 (±191.5)
	Median	50.0	44.0	75.0		50.0
	Min–Max	3.0–150.0	0.0–1000.0	0.0–1800.0		0.0–1800.0

AD, atopic dermatitis.

### Discussion

The results of the ECLA study show a considerable consumption of medical and non-medical products specifically associated with

AD. Most of the patients have used emollients and hygiene products the past 12 months. These products are often considered comfort care but remain essential to the patients for dealing

with a flare-up of the disease. Even though the expenditures associated with the consumption of emollients are the highest, the ones generated by clothing – the need for a higher quality of clothes, more clothes to allow for higher frequency of changes because of deterioration by topical products such as emollients – have a significant impact on the out-of-pocket costs. All of these products are generally not included in the list of reimbursed products and services by health insurance, as they are not considered as care products. Consequently, they are equally less covered by supplementary insurances. Therefore, the consumption of these products solely relies on patients, which may represent a very important out-of-pocket cost. In addition, we found differences between out-of-pocket costs according to the AD severity, with results highlighting significantly higher out-of-pocket costs in patients with severe AD compared to those with moderate AD.

This study also brings information about patients' therapeutic behaviour. Despite the inconsistent evidence of the benefit of food supplements,<sup>19</sup> 18.5% of patients used any of these in the past 12 months. Moreover, the frequency of patients using dietary supplements and the corresponding out-of-pocket costs associated with it increased with the severity of the disease. When treatment is not efficient, and especially when the symptoms are severe, patients tend to turn to complementary therapies. In a study aimed to evaluate the prevalence and impact of skin disorders in France,<sup>20</sup> 9% of patients with psoriasis consulted an alternative healthcare provider. This highlights the distress of desperate patients willing to try anything to attenuate the symptoms of AD, even if the solutions are not recommended.

According to the 2017 DREES report<sup>21</sup> on health accounts, the amount of out-of-pocket costs for French households under their consumption of non-hospital treatment, medicines and other medical products reimbursed by mandatory health insurance was estimated to be €216 in 2016. On average, this corresponds to 1.2% of available household annual income.

Medical and non-medical consumptions included in the questionnaire are rarely covered in the products and services reimbursed by mandatory health insurance or supplementary health insurances. Therefore, when adding the out-of-pocket costs estimated by the study's patients to the average medical out-of-pocket costs of French households, the out-of-pocket costs of medical and non-medical consumptions not covered by health insurance for patients affected by AD amount to €267.7 for mildly affected patients, €413.6 for moderately affected patients and €705.8 for severely affected patients. This represents 2.2%, 3.4% and 5.8% of available annual income for patients affected by mild, moderate and severe AD, respectively, for those having the lowest income (<€12 000/year). This share of annual income dedicated to medical and non-medical consumption associated with the

needs relating to AD is higher than that allocated on average by French households according to DREES.

Out-of-pocket costs and supplementary insurance coverage are often correlated with social classes, which create social inequality. The cost of AD on the annual income of patients with the lowest annual incomes further widens social inequalities. In addition, this economic burden may be too important for some and sometimes implies a giving up on health care and low adherence to treatment. It also creates social inequalities in access to care. Giving up leads to a worsening of the pathology that may imply an even more important cost for the patient but also for the collectivity.

Narla *et al.*<sup>22</sup> have estimated that the annual costs of AD in the United States reached \$5297 billion (2015 USD). In 2013, Eckert used the National Health and Wellness Survey American to appraise the burden of AD in the United States.<sup>23</sup> The study compared the consumption of resources and the costs of a population affected by AD with the consumption of medical care and products of a population that was not suffering from the disease. The results showed that the medical consumption of patients affected by AD was higher than that of patients for all pathologies combined, which translates to an average annual cost of AD higher than the average patient care.

In the same study, Eckert conducted a second comparison, but this time with a population affected with psoriasis. This other common chronic inflammatory skin disease shares similarities with AD. They both require patients to receive long-term treatment, and similar impairment in health-related quality of life was reported in the literature.<sup>4</sup> Waiting for further studies on the costs of AD in Europe, data on psoriasis can be a first point of comparison. The results of Eckert's study showed that the costs associated with AD are higher than those associated with psoriasis. A German study conducted in 2017<sup>24</sup> estimated the cost of psoriasis. It estimated an out-of-pocket cost for patients of €224. This out-of-pocket cost included the expenditures associated with the following resources: topical treatment, skin treatment, treatment, hospitalization fees, health care and transport.

In 2017, a French study examined socioeconomic inequalities in psoriasis.<sup>25</sup> This study showed a correlation between the severity of psoriasis and the level of education, and thus household income. In addition, the higher the severity of the disease is, the higher the associated costs and the higher the needs are, which further increases social inequalities.

These four studies show the magnitude of the economic burden skin diseases, and particularly AD, impose on patients, a burden that becomes higher as the patient's state degrades. Only 20.8% of patients benefit from full coverage by mandatory health insurance under their long-term affection (ALD). The development of this type of coverage for skin disorders could lighten the out-of-pocket costs for patients but would not eliminate the problem.



## Conclusion

The cost associated with non-medical consumption would still remain the patient's responsibility. Thus, it would seem opportune, according to us, to enlarge the perimeter of the recognized and reimbursed expenditures by mandatory health insurance for AD. Indeed, each ALD does not have the same needs. This comfort care is clinically important for both patients and the community to limit exacerbations of the disease. Thus, AD would need these essential products that are currently considered as comfort care to be recognized as vital elements of a personalized care plan.

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