

## STUDY ASSESSING THE USE OF HIGH-COST OFF-LABEL DRUGS IN THE TREATMENT OF ATOPIC DERMATITIS

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### Objectives

After several years without new drugs for atopic dermatitis, some clinical trials with monoclonal antibodies are underway.

We have found interesting to review the health results of the high cost off-label drugs used until now, in patients refractory to available treatments. Biologic therapies have been employed in the off-label treatment of dermatologic disease. Nevertheless, there are numerous case reports detailing successful and unsuccessful treatment of atopic dermatitis with these agents.

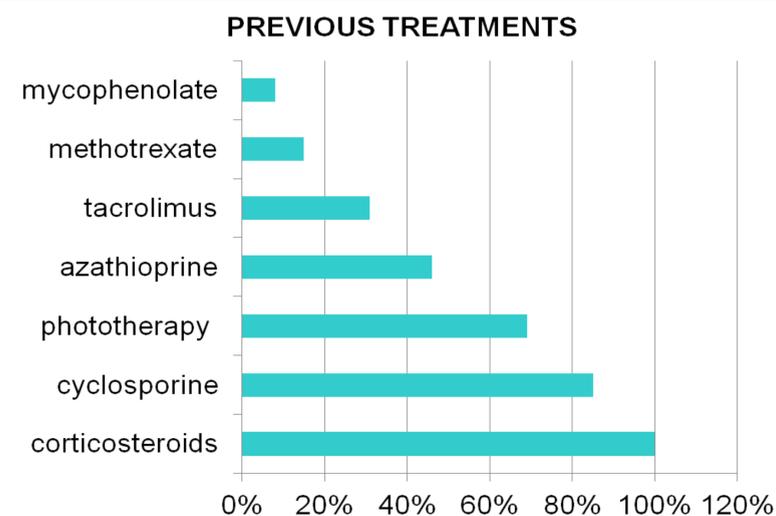
### Methods

Retrospective study from January 2010 to March 2017. The variables were: age, sex, start and finish day with study treatment and previous treatments.

### Results

A total of 13 application were approved. The drugs requested: ustekinumab (15.4%); apremilast (23.1%) and omalizumab (61.5%). The median age was 29 years, and 53.8% of patients were female.

**Previous treatments** were oral and topical corticosteroids (100%), cyclosporine (85%), phototherapy (69%), azathioprine (46%) tacrolimus (31%), methotrexate (15%) and mycophenolate (8%).



Among the patients receiving **apremilast** (23%), one had to discontinue it due to intolerance, while the other two continue on treatment. One of them has received it 8 months with good response, but the other patient has only received it 1 month, so it is early to evaluate any result.

Two patients were treated with **ustekinumab** (15%) both of them during 13 months, one stopped it due to loss of response and the other is still on treatment with stable disease.

Eight patients were treated with **omalizumab** (61, 5%). The median duration with it was 9 months. Among these patients, four of them were discontinued due to inefficacy, one was discontinued due to resolution of dermatitis and another was suspended for an adverse event. One patient never started treatment and one patient moved to another country.

Treatment	Patients	Median duration response (month)	Discontinue due to intolerance	Discontinue due to loss response
Apremilast	3	4,5	1	0
Ustekinumab	2	13	0	1
Omalizumab	8	9	1	4

### Discussion and Conclusions

Patients in this study have continued having flares despite treatment, and occasionally had to receive steroids. Based on the results, and other cases published in the literature, with similar results, we encourage development of large clinical trials with adequate power with these off-label treatments to support their uses because the cost for the health care system is huge and the evidence of its effectiveness is low.