

# Characteristics and Risk Profile of Adult Patients Treated with Apremilast Included in the British Association of Dermatologists Biologic Interventions Register (BADBIR) : A Retrospective Database Analysis (20210230)

**First published:** 12/04/2022

**Last updated:** 27/03/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS46337

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### Study ID

50015


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### DARWIN EU® study

No

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### Study countries

 Ireland

 United Kingdom

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## Study status

Finalised

## Research institutions and networks

### Institutions

#### Amgen

 United States

**First published:** 01/02/2024

**Last updated:** 27/03/2026

**Institution**

Multiple centres: 164 centres are involved in the study

## Contact details

### Study institution contact

Global Development Leader Amgen Inc.  
medinfo@amgen.com

**Study contact**

[medinfo@amgen.com](mailto:medinfo@amgen.com)

**Primary lead investigator**

Global Development Leader Amgen Inc.

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Actual: 12/12/2017

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**Study start date**

Actual: 12/12/2017

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**Data analysis start date**

Actual: 06/01/2022

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**Date of final study report**

Planned: 01/02/2023

Actual: 01/03/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Regulatory

**Was the study required by a regulatory body?**

No

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

Study type

Study type list

**Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The main objective of this study is to describe the profile of patients diagnosed with psoriasis receiving apremilast in routine clinical practice.

## Study Design

### **Non-interventional study design**

Other

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### **Non-interventional study design, other**

Retrospective database study

## Study drug and medical condition

### **Medicinal product name**

OTEZLA

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### **Medical condition to be studied**

Psoriasis

## Population studied

### **Short description of the study population**

Patients aged  $\geq 18$  years diagnosed with psoriasis treated with apremilast identified from the British Association of Dermatologists Biologic Interventions Register (BADBIR) between October 2015 to March 2021.

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### **Age groups**

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
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### **Special population of interest**

Other

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### **Special population of interest, other**

Psoriasis patients

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### **Estimated number of subjects**

286

## Study design details

### **Outcomes**

Distribution of patients across different severity risk categorization at the time of apremilast initiation. Time from diagnosis of psoriasis to apremilast initiation, time from discontinuation of the most recent prior therapy for psoriasis to apremilast initiation.

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### **Data analysis plan**

Continuous variables will be presented with the mean and standard deviation, median and inter-quartile range (IQR), and range. Categorical variables will be presented as the number and proportion in each category. No formal statistical comparisons or significance testing are planned.

## Documents

## Study results

[20210230 Abstract ORSR\\_Redacted.pdf](#) (352.26 KB)

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## Data management

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### Data source(s), other

British Association of Dermatologists Biologic Interventions Register (BADBIR)  
United Kingdom

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### Data sources (types)

[Disease registry](#)

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No