

PSOLEMEE - Localized psoriasis: a pharmaco-economic evaluation

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General

Identification

Detailed name Localized psoriasis: a pharmaco-economic evaluation

Sign or acronym PSOLEMEE

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CCTI-RS 08.493bis, CNIL 908462

General Aspects

Medical area Dermatology, venereology

Health determinants Medicine

Keywords cost, pharmaco-economic study, Psoriasis, quality of life, cohort, pharmacoepidemiology, Department of Pharmacology, Bordeaux

Scientific investigator(s) (Contact)

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Organization Université Bordeaux

Collaborations

Funding	
Funding status	Private
Details	Laboratoire GENEVRIER
Governance of the database	
Sponsor(s) or organisation(s) responsible	Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen
Organisation status	Public
Additional contact	
Main features	
Type of database	
Type of database	Study databases
Study databases (details)	Longitudinal study (except cohorts)
Database recruitment is carried out by an intermediary	A selection of health care professionals A selection of health institutions and services
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Two independent observational cohorts of patients with chronic plaque psoriasis were formed. The first, "physician cohort", was composed of patients from a random sample of general practitioners and dermatologists (hospital and non-hospital). The second, "association cohort", was composed of patients selected through the website of a psoriasis patient association.
Database objective	
Main objective	The main objective of this study was to evaluate the cost of psoriasis care for patients corresponding to the target population of BETESIL®, i.e. those suffering from chronic plaque psoriasis, localized in areas difficult to treat (knees, elbows, and anterior surface of the tibia, not exceeding 5% of body surface area).
Inclusion criteria	Patient aged 18 years or above; Patient with chronic plaque psoriasis; Patient with plaques located in places difficult to treat (knees, elbows, and anterior

tibia, not exceeding 5% of the body surface area);
 Patient able to understand or complete the study
 questionnaires; patient who can be followed for 6
 months; patient agreeing to participate in the study.

Population type

Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years) Great age (80 years and more)
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Population covered	Sick population
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Gender	Male Woman
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Geography area	National
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Detail of the geography area	Dermatologists and general practitioners in France
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Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2009
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Date of last collection (YYYY or MM/YYYY)	2010
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Size of the database

Size of the database (number of individuals)	< 500 individuals
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Details of the number of individuals	475
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Data

Database activity	Data collection completed
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Type of data collected	Clinical data Declarative data Administrative data
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Clinical data (detail)	Direct physical measures
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Declarative data (detail)	Paper self-questionnaire Phone interview
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Administrative data (detail)	Name, first name, home address, email address, phone number
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health care consumption and services Quality of life/health perception
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption
Procedures	
Data collection method	The inclusion data were collected by physicians or dermatologists (medical questionnaire), by patients (self-administered questionnaire) and CRA (telephone questionnaire). During the follow-up at 3 and 6 months, data were collected by patients (self-administered questionnaire) and CRA (telephone questionnaire).
Participant monitoring	Yes
Details on monitoring of participants	Patients were contacted by post at 3 and 6 months to complete a standard self-administered questionnaire (general data regarding psoriasis, quality of life) and by a CRA to complete a standard telephone questionnaire (drugs and cosmetics, consultations, examinations, surgery, hospitalization, sick leave, phototherapy, spa therapy).
Links to administrative sources	No
Promotion and access	
Promotion	
Access	
Terms of data access (charter for data provision, format of data, availability delay)	A study report was delivered to the pharmaceutical company after validation by the study Scientific Committee. Ownership of study data is the subject of an agreement between the University Bordeaux Segalen and the pharmaceutical company. Terms for third-party access to the database are to be defined.
Access to aggregated data	Access on specific project only

Access to individual data

Access on specific project only