

# ESTIMATION OF PATIENTS WITH PSORIASIS POTENTIALLY ELIGIBLE TO BIOLOGIC AGENTS AND NOT CURRENTLY TREATED WITH THESE THERAPIES: ANALYSIS OF REAL-WORLD DATA IN ITALY

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## BACKGROUND AND OBJECTIVES

Psoriasis (PSO) is a chronic and disabling skin disease with a negative impact on patients' quality of life. Although the disease can occur at any age, the most commonly affected age range is between 50 and 69 years [1]. In Italy, the overall estimated prevalence of PSO is 1.8–3.1%, with some variabilities in different geographic areas [2]. Evidence has shown that, in front of the growing availability of biological anti-psoriatic agents, these novel drugs are often underused or discontinued among PSO patients [3].

This is a real-world data analysis in Italy to estimate the number of patients with PSO potentially eligible for biologics.

## METHODOLOGY

An observational analysis was performed on administrative databases of a sample of Italian Entities, covering 11.3% of Italian population (Figure 1).

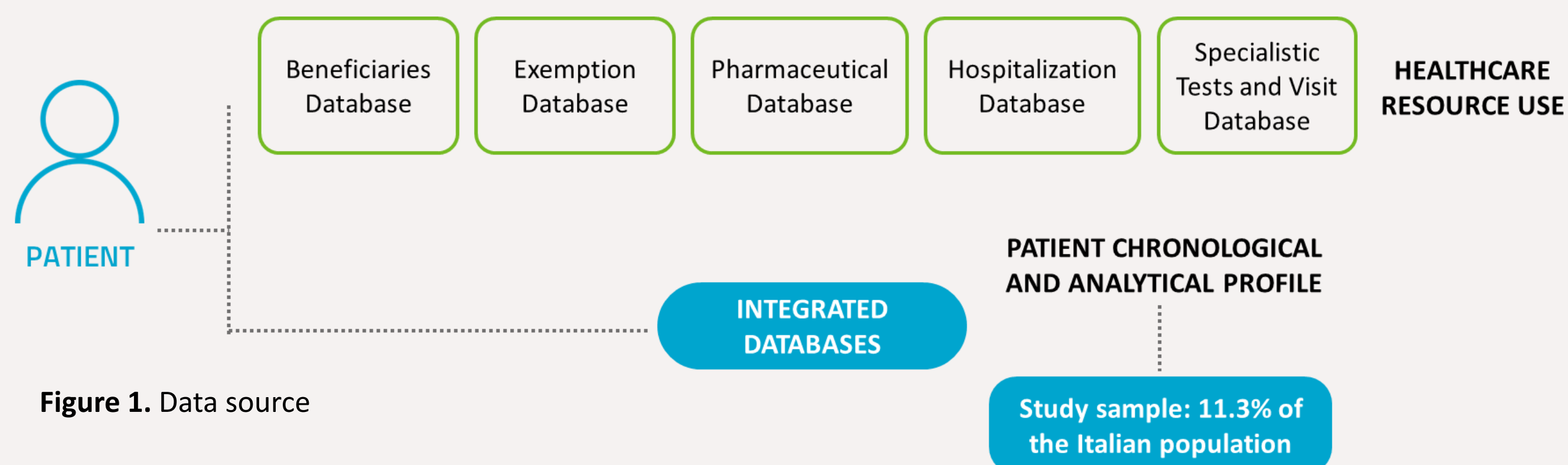


Figure 1. Data source

## STUDY POPULATION

Between 2010 and 2020 (inclusion period), PSO patients were identified by:

- at least one prescription of topical antipsoriatic drugs (ATC code D05A), **OR**
- exemption for PSO (code 045.696.1), **OR**
- at least one PSO hospitalization (discharge diagnosis code ICD-9-CM 696.1).

The index-date was that as the first PSO identification across inclusion period. Eligibility for biologics was evaluated prior to index-date (characterization period) if meeting one or both criteria [4], described in Table 1.

Table 1. Eligibility criteria for biologic treatment used in the analysis for PSO patients.

CRITERIA	PROXY OF IDENTIFICATION
<b>A. FAILURE OF AT LEAST ONE SYSTEMIC CONVENTIONAL DRUGS</b> Defined as patients with psoriasis, not on biological treatment with at least 1 previous treatments with conventional systemic drugs	Patients with previous treatments with systemic conventional drugs (indicated below), evaluated during the whole period available • Conventional drugs to consider*: Acitretin (ATC code D05BB02); Cyclosporin (ATC code L04AD01); Methotrexate (ATC codes L01BA01, L04AX03); Dimethyl fumarate (ATC code L04AX07)
<b>B. PATIENTS WITH ONSET OF PSORIATIC ARTHRITIS (PsA) AFTER OR BEFORE PSO</b> Defined as patients with a progression of PSO toward arthritic symptomatology and therefore with a diagnosis of PsA.	PSO patients with onset of PsA, identified by: • the presence of at least one <b>HOSPITALIZATION</b> for PsA in which the ICD-9-CM code 696.0 code is indicated at each level among the discharge diagnoses, <b>AND/OR</b> • the presence of an <b>EXEMPTION</b> code for PsA (exemption code 045.696.0) The diagnosis of PsA will be assessed both before and after that of PSO.

Co-morbidities, referred as contraindications for conventional treatments [4], were also recorded.

To have an epidemiological estimation on national scale, data were re-proportioned considering the entire Italian population.

## REFERENCES

- Boehncke WH & Schön MP. Psoriasis. Lancet. 2015. doi: 10.1016/S0140-6736(14)61909-7.
- Prignano F, et al. Epidemiology of Psoriasis and Psoriatic Arthritis in Italy—a Systematic Review. Curr Rheumatol Rep. 2018. doi: 10.1007/s11926-018-0753-1.
- Pilz AC, et al. Despite large choice of effective therapies: Individuals with psoriasis still seem undertreated. J Dtsch Dermatol Ges. 2021. doi: 10.1111/ddg.14387.
- Gisondi P, et al. Italian guidelines on the systemic treatments of moderate-to-severe plaque psoriasis. J Eur Acad Dermatol Venereol. 2017. doi: 10.1111/jdv.14114
- https://www.gazzettaufficiale.it/atto/serie\_generale/caricaPdf?cdimg=17A0208800100010110001&dgu=2017-03-20&art.dataPubblicazioneGazzetta=2017-03-20&art.codiceRedazionale=17A02088&art.num=1&art.tiposerie=SG

## DRUGS AND TREATMENTS FOR PSO

The drugs and treatments for PSO considered in the present analysis during the available period (2010-2020) are listed below, and patients were defined **treated** based on prescriptions of these treatments.

TOPICAL DRUGS:	BIOLOGICAL DRUGS :
<ul style="list-style-type: none"> <li>Topical antipsoriatic drugs (ATC code D05A)</li> </ul>	<ul style="list-style-type: none"> <li>Adalimumab (ATC code L04AB04)</li> <li>Apremilast (ATC code L04AA32)</li> <li>Brodalumab (ATC code L04AC12)</li> <li>Certolizumab (ATC code L04AB05)</li> <li>Etanercept (ATC code L04AB01)</li> <li>Guselkumab (ATC code L04AC16)</li> <li>Infliximab (ATC code L04AB02)</li> <li>Ixekizumab (ATC code L04AC13)</li> <li>Risankizumab (ATC code L04AC18)</li> <li>Secukinumab (ATC code L04AC10)</li> <li>Tildrakizumab (ATC code L04AC17)</li> <li>Ustekinumab (ATC code L04AC05)</li> </ul>
CONVENTIONAL SYSTEMIC DRUGS/TREATMENTS:	
<ul style="list-style-type: none"> <li>Acitretin (ATC code D05BB02)</li> <li>Cyclosporin (ATC code L04AD01)</li> <li>Methotrexate (ATC codes L01BA01, L04AX03)</li> <li>Dimethyl fumarate (ATC code L04AX07)</li> <li>Phototherapy [PUVA (procedure code 99.82.2) and narrowband UVB (procedure code 99.82.1)]</li> </ul>	

## RESULTS

### EPIDEMIOLOGY DATA

Within the study sample, **161,650 patients with a diagnosis of PSO** were identified during the period of data availability, corresponding to an estimated overall prevalence of **2% in the overall population** and **2.4% in the adults** (Figure 2).

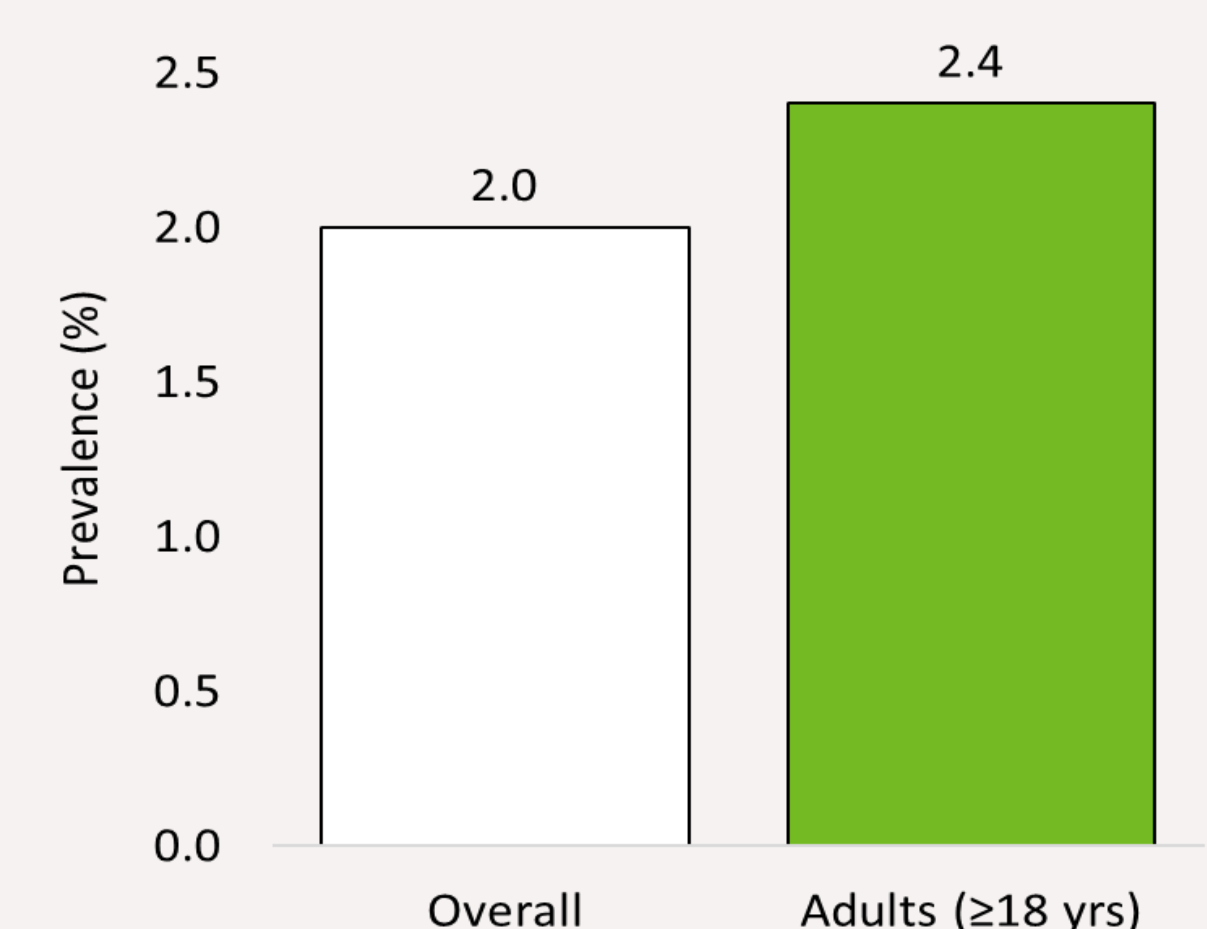


Figure 2. Estimated prevalence of PSO in the overall study population and in adults.

## ESTIMATES OF POTENTIAL ELIGIBILITY TO BIOLOGIC TREATMENTS AND PROJECTION ON THE ITALIAN POPULATION

Of the **161,650 patients with a diagnosis of PSO** found in the analysis, up to **99% (n=160,124)** were treated with drugs indicated for PSO, about 4% (n=6,371) of them with biologic drugs and 96% (n=153,753) with non-biologic drugs. About 1% of the confirmed PSO patients (n=1,526) did not receive any drug indicated for the disease.

Applying the **eligibility criteria**, **6,098 PSO patients (approximately 4% of the total study population)** resulted as potentially eligible for treatment with biologic drugs (Figure 3A).

These data, re-proportioned to the **entire national population**, suggest that considering the Italian population at 2020 (n=59.236.213), there are about **1.43 million PSO patients**, of them 1.41 million (99%) being treated: 1.35 million (95%) with no-biologic therapies, 56,319 (3.9%) with biologics, while 13,490 (1%) remain untreated (Figure 3B).

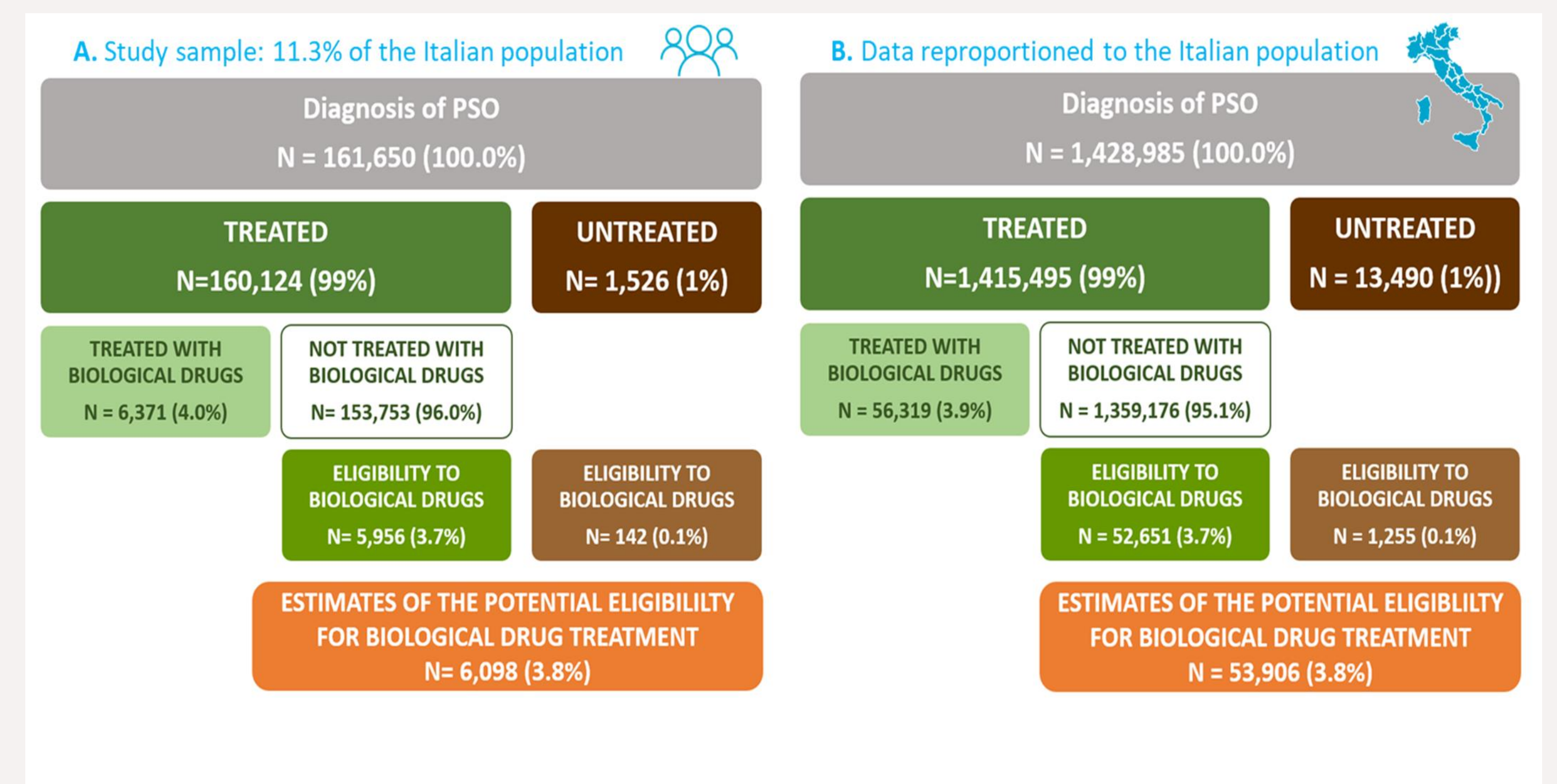


Figure 3. Treatment patterns for PSO in the study sample (A) and projection on the Italian population (B).

In Italy, **53,906 (3.8% of PSO patients)** met at least one criterion for eligibility to biologics, specifically 25% met the eligibility criterion A (failure to conventional treatments), and 68% the criterion B (PsA co-diagnosis), and 7% met both criteria.

Among patients potentially eligible, **26% and 24% had 1 or 2 comorbidities, respectively**, and 30% presented 3 or more comorbidities (data not shown).

## CONCLUSIONS

This analysis, carried out in a **real Italian clinical practice setting**, estimated at national level PSO patients potentially eligible for biologics. The results show that about 4% of PSO patients presented at least one or more eligibility criteria for these therapies. Additionally, nearly 30% exhibited a complex clinical profile with multiple comorbidities.

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