Economic Value of Dupilumab and Advanced Therapeutics in Patients with Type 2 Inflammatory Diseases in Italy: An Estimation of Healthcare Resource Utilisation Cost Offsets

DUPILUMAB

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Background

- Type 2 (T2) inflammation is a common pathway for co-existing inflammatory diseases such as atopic dermatitis (AD), asthma and chronic rhinosinusitis with nasal polyps (CRSwNP).[1]
- Dupilumab, an interleukin (IL)-4/IL-13 antagonist, received approval in Europe for treating patients with these T2 inflammatory diseases (AD in 2017; asthma in 2019; and CRSwNP in 2019).[2] Additionally, multiple other advanced therapeutics (ADTHs) exist for the treatment of different T2 inflammatory diseases in Europe.[3]
- As T2 inflammatory diseases impose a significant healthcare resource utilisation (HCRU) and cost burden,[3] it is crucial to evaluate the potential cost offsets due to an increased uptake of dupilumab or other ADTHs.

Objective

- **To estimate cost offsets from reductions in HCRU with ADTHs, including dupilumab in patients with AD, asthma, and CRSwNP, using a budget-impact model from the perspective of the Italian National Health Services (NHS) over a 1-year time horizon.**

Conclusions

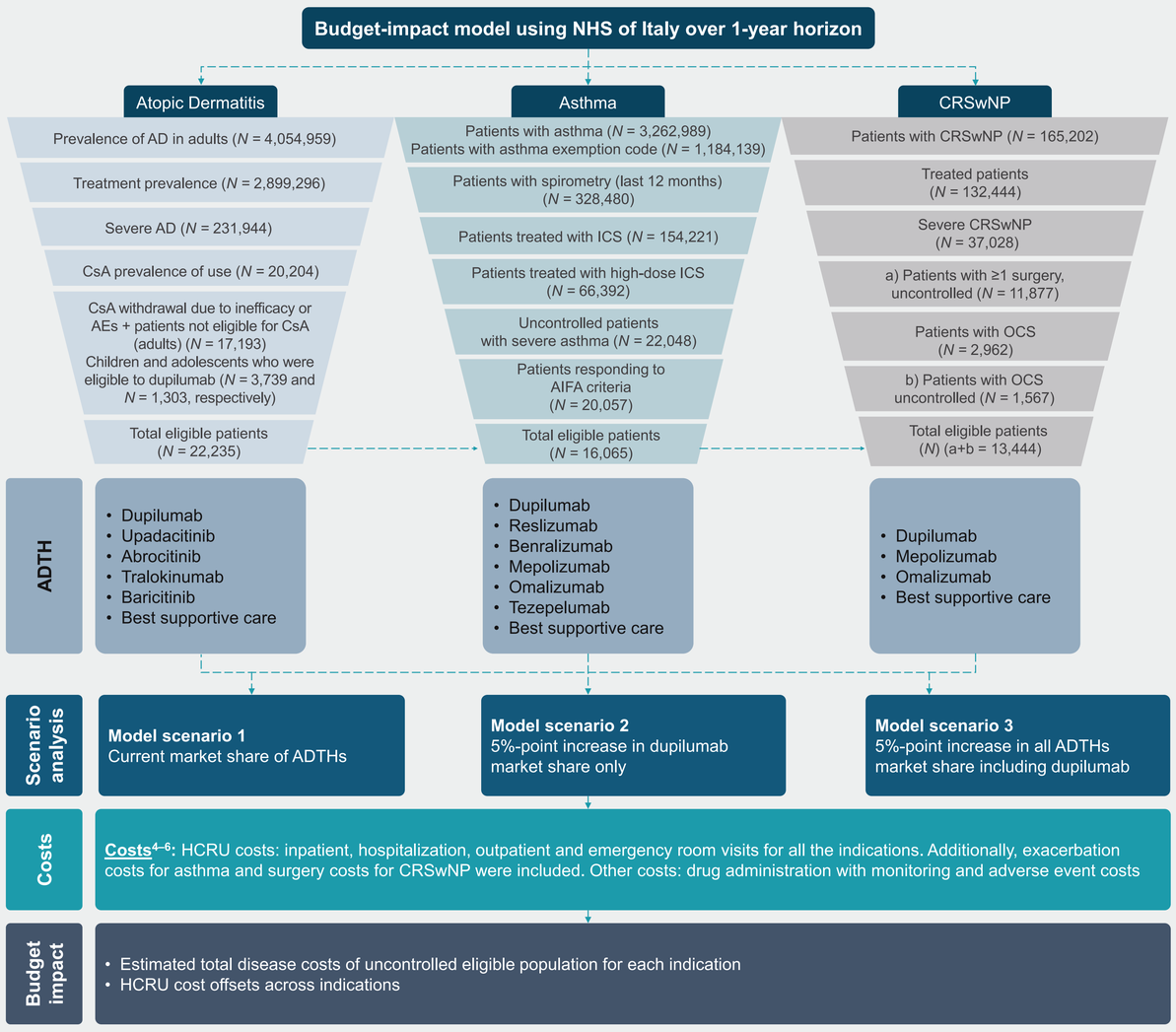
- **This model indicates that the increased use of ADTHs leads to substantial HCRU cost offsets across AD, asthma, and CRSwNP in Italy. These expected HCRU cost offsets are larger if the increased use is restricted to only dupilumab, demonstrating its comprehensive economic value across multiple T2 inflammatory diseases.**
- **The results should be interpreted with caution due to the following: the estimated costs of uncontrolled diseases were calculated at different times using various databases; indirect costs were excluded, limiting the economic burden assessment; and variability in disease management costs, including HCRU, may affect generalisability to real-world settings.**

METHODS & RESULTS

Study design

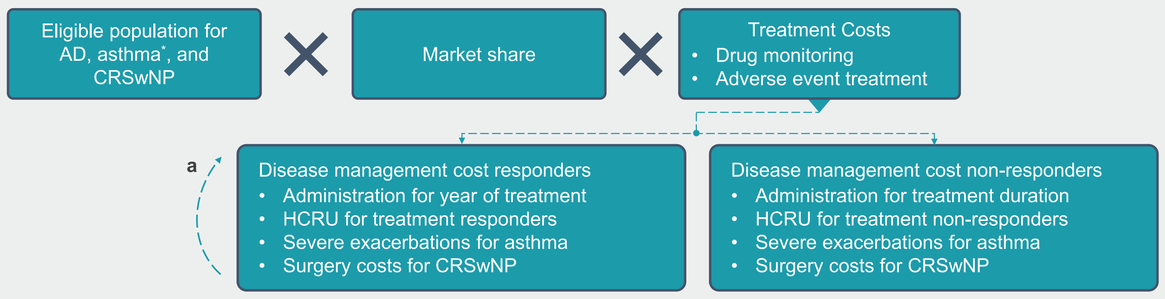
- We examined the budget impact of varying uptake levels of dupilumab and of other ADTHs (per different projected market shares), and adapted it to the perspective of NHS Italy, using an excel-based model.
- Patients aged ≥6 years with AD, ≥12 years with asthma, and ≥18 years with CRSwNP, who were eligible for ADTHs, were estimated using the Italian epidemiology data. The model overview and modelling approach are illustrated in **Figures 1** and **2**, respectively.

Figure 1. Model overview



Note: Costs (2022 Italian euros) are sourced from the perspective of the NHS of Italy serving 1 million members. Sources included to derive ADTHs eligible population were ISTAT, summaries of prescribing characteristics, published literature, and data on file from Sanofi/Regeneron Pharmaceuticals, Inc.
AD, atopic dermatitis; ADTHs, advanced therapeutics; AE, adverse event; AIFA, Agenzia Italiana del Farmaco; CRSwNP, chronic rhinosinusitis with nasal polyps; CsA, Cylosporin A; HCRU, healthcare resource utilisation; ICS, inhaled corticosteroid; NHS, National Health Services; OCS, oral corticosteroid.

Figure 2. Modelling approach



*An additional OCS dependant subgroup was included with treatment costs of HCRU for both responders and non-responders for asthma population.
[a]Treatment responders are assumed to continue treatment through the following model years, until they discontinue treatment at an indication specific treatment discontinuation rate.
AD, atopic dermatitis; CRSwNP, chronic rhinosinusitis with nasal polyps; HCRU, healthcare resource utilisation; OCS, oral corticosteroids.

Clinical efficacy inputs

- Clinical inputs were based on efficacy outcomes: AD: Eczema Area and Severity Index-75 at 16 weeks; asthma: annualised exacerbation rate; and CRSwNP: nasal polyp score improvement ≥1 at 24 weeks, based on the published indirect treatment comparisons between dupilumab and other ADTHs.[7–14]
- Additionally, the asthma group included an oral corticosteroid (OCS) dependent subgroup with a response criterion of achieving OCS reduction of ≥50%.

Scenario analysis

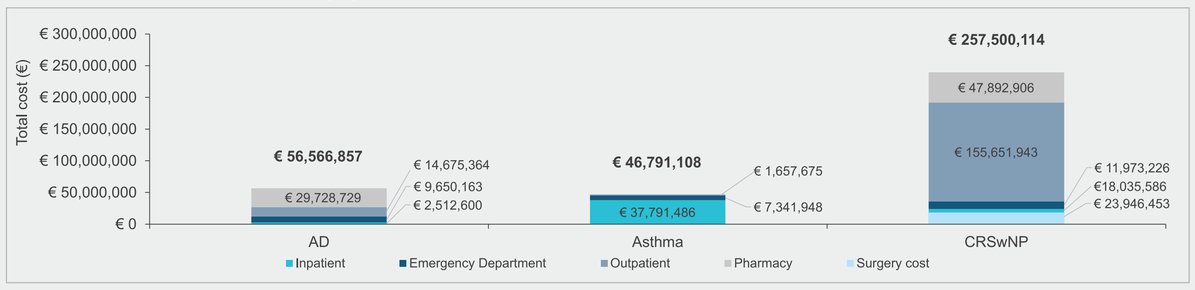
- Following hypothetical scenarios were analysed (**Figure 1**):
  - Model scenario 1: the current market with 2024 market shares
  - Model scenario 2: assuming a 5%-point increase in dupilumab uptake
  - Model scenario 3: assuming a 5%-point increase in the uptake of all ADTHs, including dupilumab, proportionally based on their current market shares
- The increases were assumed from eligible patients currently receiving the best supportive care treatment.

Results

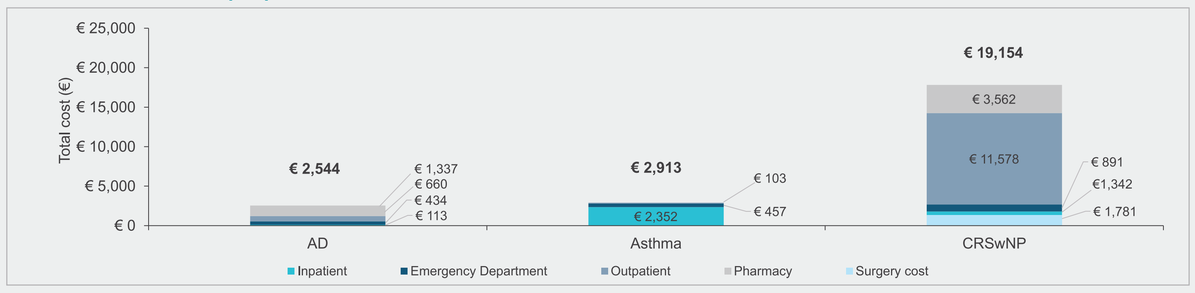
- A total of 22,235 patients with AD, 16,065 patients with asthma, and 13,444 patients with CRSwNP were included in the model **(Figure 1)**.
- The estimated total disease management medical costs for uncontrolled eligible patients with AD, asthma and CRSwNP are illustrated in **Figure 3**.

Figure 3. Estimated total disease management costs of uncontrolled* eligible population (per indication)

A. Estimated total cost for overall population



B. Estimated total cost per patient



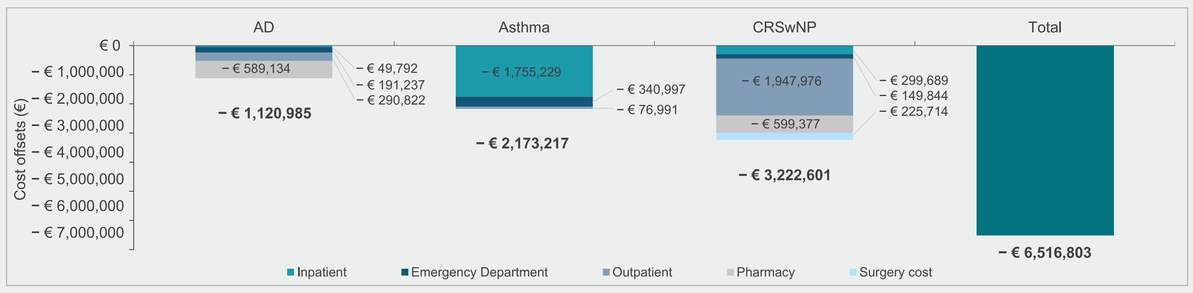
*Uncontrolled patients: AD: Moderate-to-severe AD patients; Asthma: ≥2 severe exacerbations per year despite receiving standard treatment; and CRSwNP: severe patients without adequate disease control despite use of OCS and or surgery.
AD, atopic dermatitis; CRSwNP, chronic rhinosinusitis with nasal polyps; HCRU, healthcare resource utilization; OCS, oral corticosteroid; SA, severe asthma.

Scenario analysis

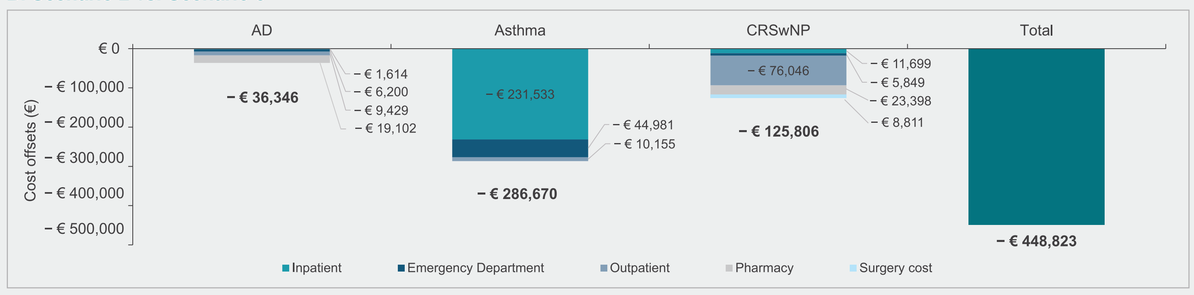
- Increasing the uptake of dupilumab by 5%-point was estimated to generate HCRU cost offsets of € 6,516,803 (**Figure 4A**), compared to the current market (€ 246,822,396 vs. € 253,339,200; **Table 1**).
- Dupilumab continued to have higher HCRU cost offsets (€ 448,823; **Figure 4B**), even after proportional 5%-point increase in all ADTHs (€ 246,822,396 vs. € 247,271,220; **Table 1**).

Figure 4. HCRU cost offsets across all three indications (AD, asthma, and CRSwNP) with (A) 5%-point increase in dupilumab market share only and (B) 5%-point proportional increase in all ADTHs market share including dupilumab

A. Scenario 2 vs. Scenario 1



B. Scenario 2 vs. Scenario 3



AD, atopic dermatitis; ADTHs, advanced therapeutics; CRSwNP, chronic rhinosinusitis with nasal polyps; HCRU, healthcare resource utilisation.

Table 1. Total costs in different scenarios for all three indications (AD, asthma, and CRSwNP)

AD, asthma, and CRSwNP	Cost category		
Budget year (2023)	**Administration and monitoring**	**Adverse events**	**HCRU**
Scenario 1: Costs as per 2024 market share	€ 573,259	€ 644,397	€ 253,339,200
Scenario 2: Costs by assuming a 5%-point increase in dupilumab share only	€ 573,259	€ 691,276	€ 246,822,396
Scenario 3: Total ADTHs market share assuming a 5%-point increase in the uptake of all ADTHs	€ 605,722	€ 685,623	€ 247,271,220

AD, atopic dermatitis; ADTHs, advanced therapeutics; CRSwNP, chronic rhinosinusitis with nasal polyps; HCRU, healthcare resource utilisation.

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ACKNOWLEDGEMENTS
Medical writing support was provided by Pudi Chiranjeevi and Ali Nasir Siddiqui from Sanofi.

FUNDING
This study was sponsored by Sanofi and Regeneron Pharmaceuticals, Inc.

CONFLICTS OF INTEREST
GF is an employee at PharmaLex S.p.A. **JT**, **FJ**, **GB**, and **MD** are employees of Sanofi and may hold stocks and/or stock options in the company. **LD** is an employee of Aixial Group and a paid consultant to Sanofi. **ZW** and **AK** are employees of Regeneron Pharmaceuticals, Inc. and may hold stocks and/or stock options in the company. **LF** and **W-HC** were employees of Sanofi at the time of study execution and abstract development.

Poster presented at the International Society for Pharmacoeconomics and Outcomes Research Europe 2024 (ISPOR EU 2024), November 17–20, Barcelona, Spain.