HPR153

THE REIMBURSEMENT STATUS OF USTEKINUMAB ACROSS HTAs: A GLOBAL PERSPECTIVE

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Introduction

- Health technology assessment (HTA) agencies assess the economic value of new therapies to inform reimbursement decisions
- Ustekinumab is a safe and effective IL-12/IL-23 inhibitor indicated for the treatment of plaque psoriasis (PsO), psoriatic arthritis (PsA), Crohn's disease (CD), and ulcerative colitis (UC)
- High costs associated with reference product biologics such as ustekinumab can impact reimbursement status, **which can limit overall patient access**

Objective

To assess the HTA reimbursement decisions of ustekinumab's reference product across adult indications (CD, UC, PsO, PsA) in the following countries:

AUS CAN FRA IRL ITA SCO SWE UK

Methods

- The NAVLIN database[1] was used to assess the reimbursement decisions.
- In countries with data not accessible through NAVLIN, a literature search was performed to assess reimbursement
- HTA decisions were classified using the following categories:
  - full reimbursement (according to label)
  - partial reimbursement (e.g., based on disease severity)
  - do not recommend

Results

- CD and UC were fully reimbursed for all countries where reports were found (**Table 1**)
- Four countries reported a partial recommendation for PsO; three countries reported a partial recommendation for PsA with one country advising a "Do Not Recommend"

Table 1: HTA recommendations for ustekinumab from regions included in review

Country	Recommendation Organization	Crohn's Disease	Ulcerative Colitis	Plaque Psoriasis	Psoriatic Arthritis
Australia	PBAC	2017-03-01[2]	2022-07-01[3]	**Severity** 2009-11-01[4]	**Severity** 2015-11-01[5]
Canada	CDA*	2017-03-21[6]	2020-07-16[7]	**Severity** 2009-06-17[8]	2014-10-20[9]
France	HAS	2023-11-08[10]	2023-11-08[10]	**Severity** 2011-06-22[10]	2023-11-08[10]
Ireland	NCPE	2017-01-11[14]	2019-12-17[15]	2009-11-01[16]	
Italy	AGENAS	2021-11-24[17]	2021-11-24[17]	2018-08-09[18]	2021-11-24[17]
Scotland	SMC	2017-07-10[19]	2020-04-13[20]	2010-02-08[21]	**Prior Tx** 2014-03-10[22]
Sweden	TLV	2024-12-13[23]	2024-12-13[23]	2024-12-13[23]	2024-12-13[23]
United Kingdom	NICE	2017-07-12[24]	2020-06-17[25]	**Prior Tx** 2017-03-03[26]	**Prior Tx** 2017-03-03[27]

* Please note that the CDA was previously named CADTH

Legend: Full Reimbursement; Do Not Recommend; Partial Reimbursement; No Recommendation

Highlights

The introduction of biosimilars have changed treatment guidelines and reimbursement landscapes for several countries.[28,29]

In the United Kingdom, the reimbursement of autoimmune biosimilars including adalimumab and abatacept expanded reimbursement recommendations to cover patients with moderate rheumatoid arthritis [TA175].[30]

In Canada, CADTH (now known as the CDA) did not recommend the reimbursement of PsA. Ustekinumab's reference product was covered by provincial formularies; however, many have switched to only reimbursing its biosimilars.[31,32]

Conclusion: Reimbursement decisions for reference product ustekinumab vary in PsO and PsA. As decisions are largely influenced by cost-effectiveness, use of more affordable ustekinumab biosimilars may help to improve patient access to therapies.

Disclosures: KS is an employee of Fresenius Kabi, a. manufacturer of biosimilars. KC, BRL, MAG, and NF are employees of EVERSANA, a company that receives consulting fees from Fresenius Kabi

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Abbreviations: AGENAS = Agenzia Nazionale per I Servizi Sanitari Regionali; CD = Crohn's disease; CDA = Canada's Drug Agency; HAS = Haute Autorité de Santé; HTA = health technology assessment; NA = not applicable; NCPE = National Centre for Pharmacoeconomics; NICE = National Institute for Health and Care Excellence; PsA = psoriatic arthritis; PsO = psoriasis; SMC = Scottish Medicines Consortium; PBAC = Pharmaceutical Benefits Scheme; TLV = Tandvårds- och läkemedelsförmånsverket; Tx = treatment; UC = ulcerative colitis.

References: 1. NAVLIN Global Pricing and Market Access Database (2024), Accessed: April 2024. **2.**Ustekinumab Public Summary Document – March 2017 PBAC Meeting **3.** TGA Public Summary Document – July 2022 **4.**TGA November 2009 PBAC Meeting Outcomes – Positive Recommendations **5.**TGA November 2015 PBAC Meeting – Positive Recommendations **6-7,9.** CADTH Canadian Drug Expert Committee final recommendation **8**. CEDAC Final Recommendation and Reasons for Recommendation **10.** HAS STELARA https://www.has-sante.fr/jcms/pprd_2983689/en/stelara **14.** NCPE Ustekinumab (Stelara®) for Crohn's disease; **15**. NCPE 19048 **16**. Ustekinumab (Stelara®) **2.** Smolen. *Ann Rheum Dis* 79 (6): 685-699. **17**. AGENAS DG/1403/2021 **18.** AGENAS DG/1230/2018 **19.** SMC 1250/17 **20**. SMC SMC2250 **21.** SMC 572/09 **22.** SMC 944/14 **23**. TLV 2806/2024 **24.** NICE TA456 **25**. NICE TA633 **26**. NICE TA180 **27**. NICE TA430 **28.** Moayyedi *J Can Assoc Gastroenterol* 3 (1):e1-e9 **29.** Smolen JS *Ann Rheum Dis* 82(1):3-18 **30.**NICE Guidance – [TA715] (2021), Accessed: April 2025. **31**. BC PharmaCare Drug Coverage Decision for BC PharmacCare ustekinumab biosimilars. **32.** Ontario. Biosimilars. 08-23-2024.