

Beyond the Surface: Health Technology Assessment and Reimbursement for Inflammatory or Autoimmune Disorders With Cosmetic and Dermatological Manifestations

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Background

- Health technology assessment (HTA) agencies play a pivotal role in guiding public reimbursement and pricing decisions by determining clinical effectiveness, cost-effectiveness, and overall value of health interventions.^{1,2}
- Reimbursement and approval recommendations are made independently for each country/region and may be influenced by the perspective taken by HTA bodies and stakeholders including public drug plans, physicians, and patient groups.^{1,2}
- The overarching purpose of HTA agencies is to support decisions that promote equity, efficiency, and quality within the health system.³
- It is unclear if treatments for conditions with visible but non-life-threatening manifestations, are evaluated differently by HTA bodies.
 - Chronic autoimmune conditions with a “cosmetic” manifestation such as rosacea, acne, vitiligo, and alopecia areata have impacts beyond the visible symptoms. These conditions are associated with increased risk of anxiety, depression, low self-esteem and social avoidance.^{4,5,6}
- Given the psychosocial impacts of these chronic autoimmune conditions, there is a need to better understand if treatments for these conditions are evaluated routinely by HTA agencies and whether the evaluations are consistent across jurisdictions.

Objective

- This study aimed to evaluate how treatments for chronic autoimmune conditions with perceived “cosmetic” manifestations are evaluated by HTA agencies and by public payers in Europe and Canada.

Methods

- Guidelines from HTA agencies in Canada (CDA-AMC, INESSS)^{7,8}, England (NICE)⁹, Scotland (SMC)¹⁰, France (HAS)¹¹, and Sweden (TLV)¹² were reviewed to identify evaluation frameworks and decision-making criteria for chronic autoimmune conditions with cosmetic manifestations (Table 1).

Table 1: Global HTA Bodies

HTA Body	Country
Canada's Drug Agency (CDA-AMC)	Canada
Institut national d'excellence en santé et en services sociaux (INESSS)	Canada (Québec)
National Institute for Health and Care Excellence (NICE)	England
Scottish Medicines Consortium (SMC)	Scotland
Haute Autorité de Santé (HAS)	France
Dental and Pharmaceutical Benefits Agency (TLV)	Sweden

- Publicly available HTA submissions and final recommendations for therapies indicated for rosacea, alopecia, areata, vitiligo, and acne vulgaris were evaluated (see Figure 1 for a brief description of each condition).
- For each therapy, the public reimbursement status was assessed to identify patterns in access and funding decisions across jurisdictions.
- HTA recommendations for the therapies reviewed were issued between 2004 and 2025.

Figure 1: Chronic Autoimmune Conditions with Cosmetic Manifestations

1 Rosacea

Immune-mediated inflammatory skin condition characterized by facial redness, visible blood vessels, papules, pustules, and sometimes thickened skin.¹³ It is often accompanied by burning or stinging sensations and can impact facial appearance and emotional well-being.^{4,13}

2 Alopecia areata

Autoimmune disorder targeting hair follicles, leading to well defined, non-scarring patches of hair loss on the scalp, face, or body.¹³ The sudden unpredictable onset and random visible patches of hair loss can have significant psychosocial implications.¹³

3 Vitiligo

Immune-mediated depigmentation condition where the skin loses its colour due to the immune system attacking pigment-producing cells resulting in white, clearly defined lesions on the skin.⁹ The disorder is psychologically distressing and socially stigmatizing, especially in individuals with darker skin tones.⁵

4 Acne vulgaris

Inflammatory skin condition involving dysregulation of the immune response.¹³ It is characterized by chronic or recurrent noninflammatory lesions (e.g., blackheads and whiteheads) and inflammatory lesions (e.g., papules, pustules, and nodules) typically affecting the face, neck, upper back, and chest.¹³ The condition is associated with a profound effect on quality of life.¹³

Results

HTA Guidelines

- Most HTA guidelines broadly identify the technology they review including pharmaceuticals and medical devices without excluding technologies based on type of condition being treated.
- Only INESSS guidelines specify that therapies for cosmetic or aesthetic purposes and those for the treatment of alopecia will not be reviewed.⁸

HTA Submissions

- Across the four conditions included in the evaluation, 17 therapies were identified, with reimbursement submissions varying across HTA bodies within Europe and Canada (Table 2).

- No single treatment was submitted to all six HTA agencies with several treatments for acne vulgaris submitted to only one HTA.
- Differences in regulatory approvals across regions was also observed and impacted the number of HTA submissions.
- Therapies for alopecia areata showed the most consistent HTA activity, with submissions for ritlecitinib and baricitinib received or pending across all agencies except INESSS, which has not reviewed any therapies for this indication, consistent with the exclusion criteria in the INESSS guidelines.
- SMC has reviewed the highest number of submissions encompassing therapies across all four conditions.
- CDA-AMC and HAS have also reviewed therapies for all four conditions.
- TLV has not reviewed either of the two therapies for vitiligo but has reviewed at least one therapy for the other conditions.
- NICE has not reviewed any therapies for rosacea or acne vulgaris. Ivermectin and brimonidine for rosacea were both deemed inappropriate for technology appraisal by NICE,^{14,15} suggesting that rosacea therapies are generally excluded from NICE review.

Table 2: HTA Submissions and Recommendations for Chronic Autoimmune Conditions with Cosmetic Manifestations

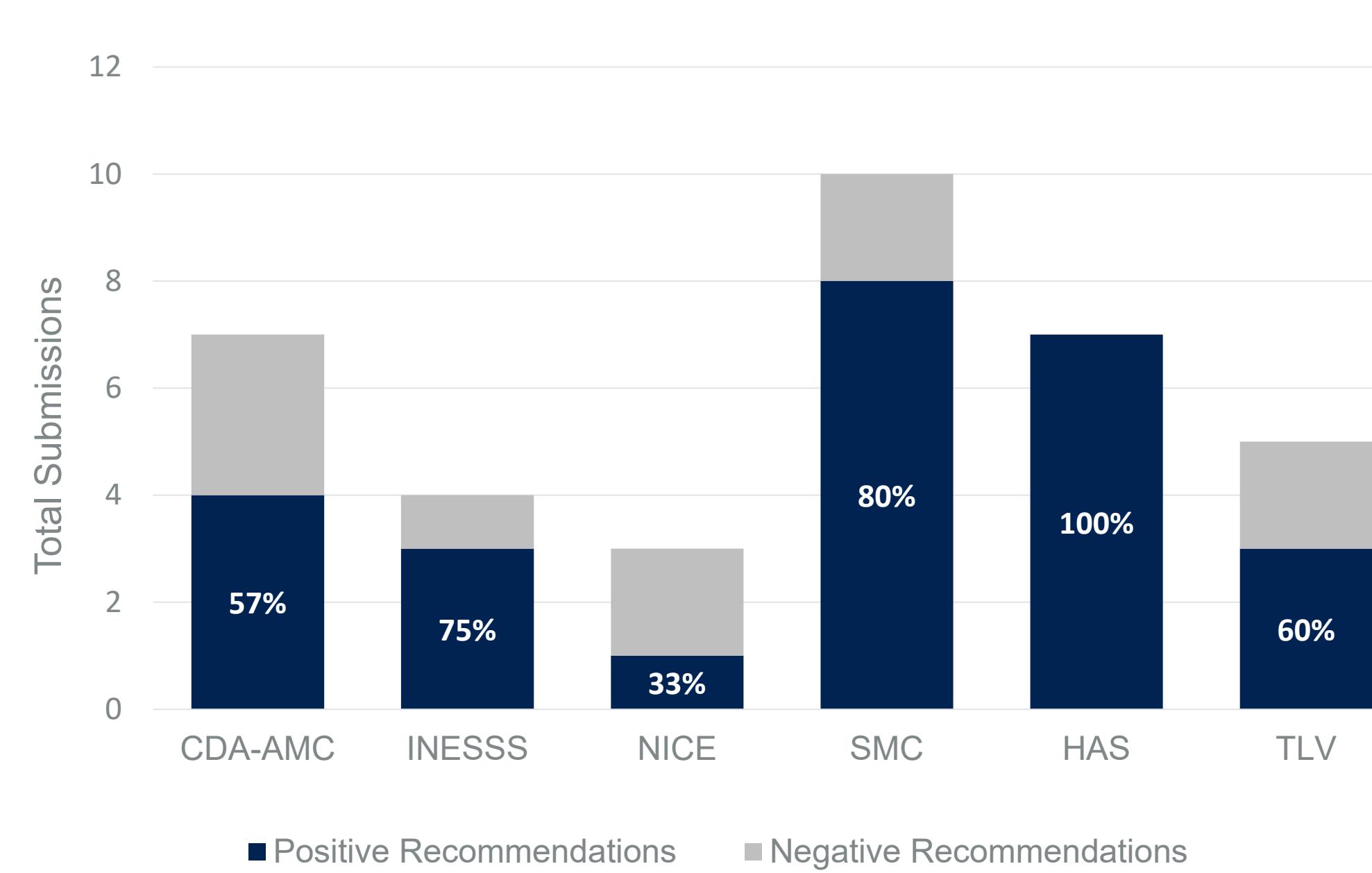
Condition	Treatment (Brand)	HTA Submitted					
		CDA-AMC	INESSS	NICE	SMC	HAS	TLV
Rosacea	Azelaic acid (Finacea)	✓	✓	—	✓	✓	✓
	Brimonidine (Mirvaso/Onreltea)	—	—	—	✓	—	—
	Ivermectin (Soolantra/Rosiver)	✓	✗	—	✓	—	✓
	Doxycycline monohydrate (Aprilon/Oracea)	✗	—	—	—	—	—
Alopecia areata	Ritlecitinib (Litfulo)	Pending	—	✓	✓	✓	✗
	Baricitinib (Olumiant)	✓	—	✗	✗	✓	✗
Vitiligo	Ruxolitinib (Opzelura)	✗	Under review	✗	✗	✓	—
	Ritlecitinib (Litfulo)	—	—	Awaiting development	—	—	—
Acne vulgaris	Clindamycin 1% / tretinoin 0.025% gel (Treclin)	NA	NA	—	✓	—	—
	Clindamycin 1% and benzoyl peroxide 5% gel (Duac)	NA	NA	—	✓	—	—
	Adapalene 0.1%/benzoyl peroxide 2.5% gel (Epiduo)	NA	NA	—	✓	✓	✓
	Adapalene 0.1%/benzoyl peroxide 2.5% gel (Casarenen)	NA	NA	—	—	✓	—
	Trifarotene (Akief)	—	—	—	✓	—	—
	Isotretinoin (Acnetrait, Contracne, Curacne, Procuta)	NA	NA	—	—	✓	—
	Isotretinoin (Epiris)	—	✓	NA	NA	NA	NA
	Clindamycin plus benzoyl peroxide and adapalene (Cabtreo)	✓	✓	NA	NA	NA	NA
	Clascoterone (Winlevi)	✗	—	—	—	—	—
	Total Submissions	7	5	3	10	7	5
	Gaps in Submissions (therapies not submitted)	4	7	11	5	8	10

NA Not approved for sale — Not submitted ✓ Positive HTA recommendation ✗ Negative HTA recommendation

HTA Recommendations

- Reimbursement recommendations differed widely across HTA bodies (Table 2; Figure 2).
- HAS consistently issued positive reimbursement recommendations for all therapies submitted.
- Also in Europe, SMC had a high (80%) positive recommendation rate with positive recommendations for all therapies except those for vitiligo.
- In contrast, other HTA bodies such as TLV were more restrictive, issuing negative recommendations for the same therapies HAS approved, specifically those targeting alopecia areata. TLV has positively recommended therapies for rosacea and one for acne.
- NICE approved only one of the two therapies for alopecia areata that were positively reviewed by HAS.
- In Canada, CDA-AMC and INESSS have recommended reimbursement for select therapies, with INESSS supporting only those for acne and one therapy for rosacea.
- While similar clinical evidence was provided to all HTAs, limitations cited by HTA bodies differed.
- Negative recommendations were attributed to a range of factors including lack of health-related quality of life data, missing or insufficient data, uncertainty regarding clinical meaningfulness, limitations in trial design and analysis, and cost-effectiveness.

Figure 2: HTA Submissions and Recommendations



Conclusion

This study identifies high variability in HTA submissions and recommendations for chronic autoimmune conditions with cosmetic manifestations. Such variability may reflect differences in how these conditions are prioritized among HTA agencies.

- It remains unclear whether the absence of HTA submissions by manufacturers for certain therapies is due to anticipated HTA challenges or the use of alternative funding pathways that do not require HTA review.
- If public access and coverage is contingent on HTA review, inequalities may arise, increasing the unmet need in these affected patient populations, potentially adding to the social stigma. However, if these therapies are made publicly available and covered through alternative pathways, inequities in access may be less of a concern.
- The findings highlight the importance of ensuring equitable access to therapies for chronic autoimmune conditions with cosmetic manifestations and greater consistency in HTA processes to avoid disparities in coverage.

Abbreviations CDA-AMC = Canada's Drug Agency; HAS = Haute Autorité de Santé; HTA = health technology assessment; INESSS = Institut national d'excellence en santé et en services sociaux; NICE = National Institute for Health and Care Excellence; SMC = Scottish Medicines Consortium; TLV = Dental and Pharmaceutical Benefits Agency.

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