## **NZDSI Position Statement on Isotretinoin**



Date: September 2025

The New Zealand Dermatological Society Incorporated (NZDSI) affirms its commitment to the safe and responsible use of isotretinoin. Isotretinoin is approved by Medsafe New Zealand and the Therapeutic Goods Administration (TGA) in Australia, and it represents the most effective therapeutic option for severe acne. The efficacy of systemic isotretinoin has been established in randomized, double-blind clinical trials, demonstrating significant reductions in acne severity and a consequent decrease in the risk of permanent scarring.<sup>1-3</sup>

The NZDSI acknowledges that the Australasian College of Dermatologists have released a position statement on isotretinoin updated as of October 2024.<sup>4</sup> This position statement has been reviewed by the executive board and adopted to the New Zealand context as many similarities exist in our clinical practice and patient base.

The recent report of the Commission on Human Medicines (CHM) Isotretinoin Expert Working Group in the United Kingdom deserves special mention as it has led to policy changes that significantly affect isotretinoin prescription in the United Kingdom.<sup>5, 6</sup>

## On methodology used to generate the CHM report

The NZDSI acknowledges that concerns have been raised regarding both the methodology and the evidence underpinning the CHM report.<sup>7, 8</sup> In particular, the included studies were not formally graded for quality, and the process by which the evidence was synthesised - if such synthesis even occurred - was not communicated with sufficient transparency.<sup>9</sup>

# On Isotretinoin and mental health

Current high-quality evidence does not support a causal relationship between isotretinoin use and suicide. A 2017 systematic review and meta-analysis of 31 studies found no significant increase in depression or suicidality in patients taking isotretinoin, and in some cohorts, mood improved as acne cleared. A Swedish nationwide cohort study of over 5,000 isotretinoin users found that the risk of psychiatric diagnoses and suicide attempts was highest in the year before treatment, reflecting the psychosocial burden of severe acne, and declined after therapy. Similar findings from large Canadian and UK population-based studies show no excess risk compared with unexposed acne patients.

Acne itself is associated with increased rates of depression, anxiety, and suicidality, particularly in adolescents and young adults. <sup>14, 15</sup> For this reason, all patients with moderate-to-severe acne should be screened for depression, with either management by the patient's general practitioner or referral to appropriate mental health support when indicated. <sup>16</sup> Isotretinoin is not contraindicated in patients with depression or other mental health issues and can improve these where acne is contributory. <sup>17, 18</sup>

## On Isotretinoin and sexual dysfunction

Current evidence is insufficient to establish a causal relationship between isotretinoin use and sexual dysfunction. <sup>19</sup> This is compounded by the lack of a standardised definition of sexual dysfunction making it impossible for comparison to be made between studies. The overall quality of the studies is low. <sup>19</sup>

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#### On health inequality particularly for Māori, Asian and Pacific people

The NZDSI is concerned that adopting policy changes proposed in the CHM report in New Zealand could reduce access to isotretinoin and exacerbate health inequities, particularly among Māori, Asian, and Pacific populations. Recent analysis of dispensing data from the New Zealand Pharmaceutical National Collection database demonstrated that prescription rates for Māori and Asian patients have increased more rapidly than for Europeans, suggesting that longstanding ethnic disparities in isotretinoin access are beginning to improve, <sup>20</sup> but this may be reversed by adopting the CHM recommendations.

The NZDSI concludes that isotretinoin remains an appropriate treatment for acne, provided that prescribing physicians remain vigilant regarding its known safety considerations. Psychiatric illness should not be regarded as an absolute contraindication; rather, treatment decisions ought to be made through shared decision-making within the framework of NICE guidelines. Concerns regarding potential sexual dysfunction should not be suggested to patients in the absence of supporting evidence; however, prescribers are encouraged to report any suspected adverse reactions to isotretinoin, or to other medications, in accordance with the Centre for Adverse Reactions Monitoring (CARM) guidelines.

We wish to avoid unnecessary harm resulting from withholding beneficial treatment from patients. Not providing treatment on the basis of assertations about harmful side effects that have been found not to be related to isotretinoin treatment by a large volume of good quality evidence puts patients at increased risk of unnecessary scarring and mental health effects from untreated acne.

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#### **Revision of this Position Statement**

This position statement reflects the best available evidence at the time of approval. It will be subject to revision under any of the following circumstances: 1) Emergence of high-quality evidence: Publication of new randomized controlled trials, systematic reviews, or large population-based cohort studies that materially alter the current understanding of isotretinoin's efficacy, safety, or risk profile. 2) Adverse event signals: Identification of new, consistent, and clinically significant safety signals reported through pharmacovigilance systems (e.g., CARM) that warrant a reassessment of risk—benefit balance. 3) Periodic review: In the absence of major new evidence, this statement will be reviewed at least every five years to ensure its continued relevance and accuracy.