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BACKGROUND

- Approximately 1% to 3% of Canadians are impacted by plaque psoriasis, an inflammatory skin condition. Since plaque psoriasis is a chronic disease, it requires control through ongoing, long-term management with topical, systemic, and/or light therapies.
- Given the heterogeneity of patients with respect to plaque psoriasis signs/symptoms, disease severity, and treatment preferences, additional and more diverse treatment choices should provide patients with more options, potentially leading to better outcomes.
- A fixed-dose lotion combination of halobetasol propionate (HP) 0.01% plus tazarotene (TAZ) 0.045% [HP/TAZ; Duobrii™; Bausch Health, Canada Inc.], which is indicated in Canada for improving the signs and symptoms of plaque psoriasis in adult patients with moderate-to-severe disease, received a notice of compliance from Health Canada in 2020.

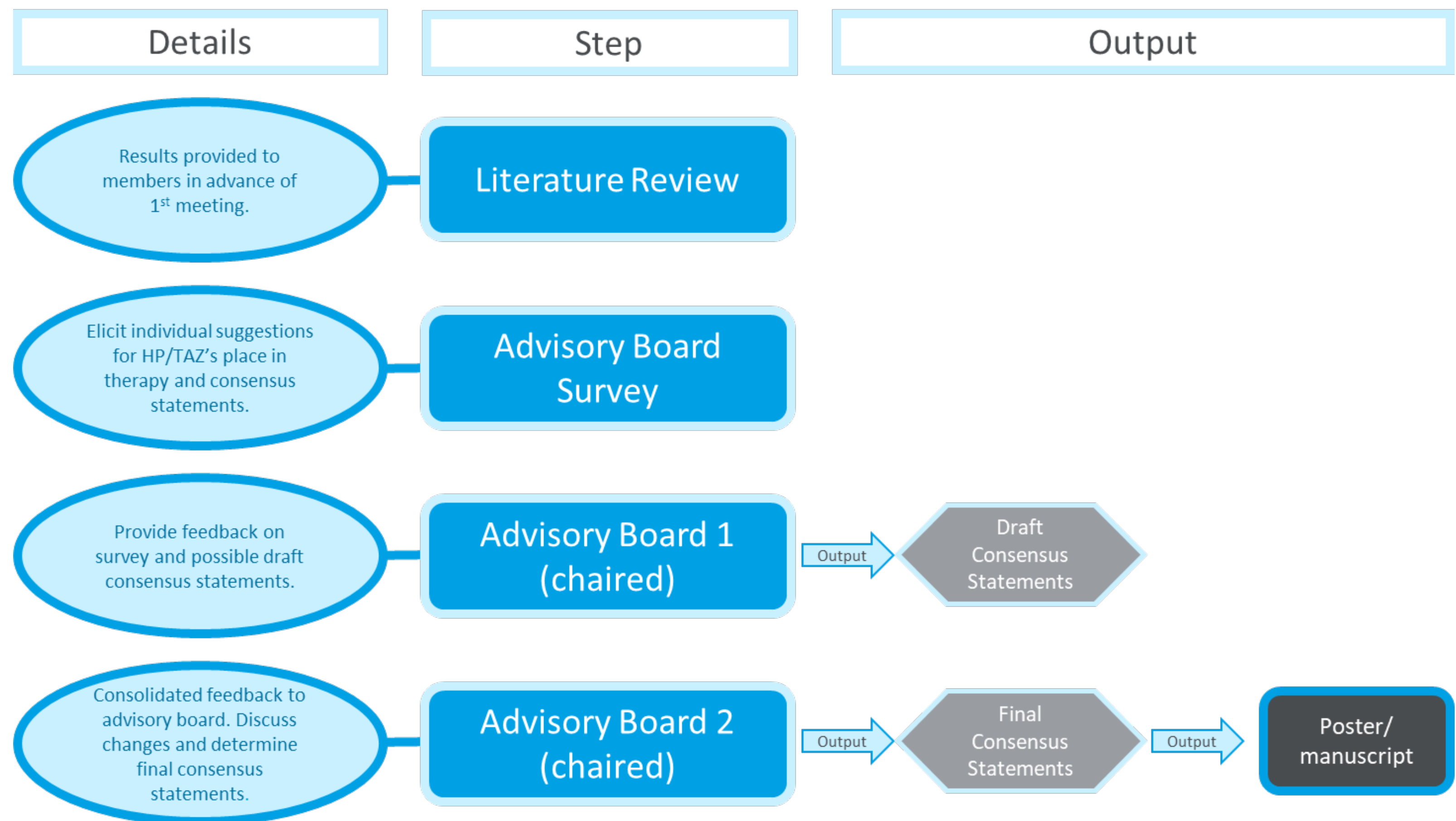
OBJECTIVES

- An expert panel of Canadian dermatologists was assembled to develop consensus statements regarding the current landscape of topical therapies for plaque psoriasis and the place in therapy of the recently approved fixed-dose HP/TAZ lotion combination in the treatment algorithm for plaque psoriasis.

METHODS

- Seven Canadian dermatologists participated in an expert panel (with one serving as the Chair). A modified nominal group technique, which combined both independent and group input from the expert panel, was used to develop the consensus statements.
- The expert panel completed surveys to elicit their independent views on the current landscape of topical therapies for plaque psoriasis in Canada.
- The first expert panel session was held to discuss the existing body of literature and develop draft consensus statements about topical therapies and the place in therapy of HP/TAZ. Independent feedback on the draft consensus statements was solicited from expert panel members prior to another expert panel session where the amended consensus statements were further discussed, edited and, finally, voted on (Dec-2021).
- Consensus was determined by the expert panel as requiring six out of seven members to anonymously vote ‘agree’ or ‘strongly’ agree on a 5-point Likert scale.

Figure 1. Consensus Statement Development Process



RESULTS

- Expert panel members composed 20 statements which all achieved consensus (see Table 1 and 2 for statements and voting results) based on the current literature as well as their clinical opinions and professional experiences treating patients with plaque psoriasis.
- The consensus statements were categorized into two main groups: those pertaining to the general topical therapy landscape (Table 1) and those pertaining specifically to HP/TAZ (Table 2), with each further organized into four themes (unmet needs, safety/limitations, efficacy and convenience/acceptability/accessibility).

RESULTS (CONTINUED)

Table 1. General Topical Treatment Landscape: Statements and Voting Results

| Unmet Needs |
|---|
| <p>1. Many patients with plaque psoriasis are undertreated, feel dissatisfied with treatment, and feel their condition is not well controlled. There is an unmet need for accessible, safe and efficacious topical therapies that would allow patients to be adequately treated, feel satisfied with treatment, and believe they have control of their condition. “Voting: 7/7 strongly agree”</p> <p>2. Given that plaque psoriasis is a chronic disease with no cure, the continuous need for safe and effective topical therapies is important. “Voting: 6/7 strongly agree; 1/7 agree”</p> |
| Safety / Limitations |
| <p>3. Many current topical therapies for plaque psoriasis have limitations, such as duration of use and safety concerns. “Voting: 5/7 strongly agree; 1/7 agree; 1/7 neutral”</p> |
| Efficacy |
| <p>4. A common treatment goal for both treating physicians and patients with plaque psoriasis is to achieve clear or almost clear skin. “Voting: 7/7 strongly agree”</p> <p>5. Rapid onset of action is important for topical therapies, as it may motivate adherence to treatment. “Voting: 5/7 strongly agree; 2/7 agree”</p> <p>6. High efficacy and an improved safety profile are vital in the treatment of plaque psoriasis allowing long-term disease control and prolonged treatment-free intervals. “Voting: 4/7 strongly agree; 3/7 agree”</p> |
| Convenience / Acceptability / Accessibility |
| <p>7. Many patients prefer to treat plaque psoriasis with topical therapies, giving them a sense of control and flexibility. “Voting: 4/7 strongly agree; 2/7 agree; 1/7 neutral”</p> <p>8. The dosing schedule, vehicle properties and cosmetic acceptability impact adherence. Most patients with plaque psoriasis value infrequent application and a product that is easily absorbed and non-greasy, -odorous or -staining. “Voting: 7/7 strongly agree”</p> <p>9. Localized plaque psoriasis is often managed by primary care providers. Referral to dermatologists may be difficult to secure. Accessible topical therapies are needed to enhance disease treatment. “Voting: 6/7 strongly agree; 1/7 neutral”</p> |

CONCLUSION

- Through both independent reflection and group discussions, the expert panel of dermatologists agreed that there is a need for additional first-line therapies for plaque psoriasis.
- The consensus statements supported the premise that first-line therapy with HP/TAZ addresses several current unmet needs in treating patients with plaque psoriasis.
- Furthermore, HP/TAZ has been found to be effective and safe in treating moderate-to-severe plaque psoriasis and, due to its cosmetically acceptable vehicle and once-daily administration, HP/TAZ presents a favourable opportunity for patient acceptance and treatment adherence.

Table 2. HP/TAZ Fixed-Combination Lotion: Statements and Voting Results

| Unmet Needs |
|--|
| <p>10. HP/TAZ can be used in patients with moderate-to-severe plaque psoriasis as a first-line treatment or as an adjunctive treatment for residual disease that persists despite systemic therapy or phototherapy. “Voting: 6/7 strongly agree; 1/7 agree”</p> <p>11. As per clinical experts’ opinion, HP/TAZ may have therapeutic benefits for difficult-to-treat sites such as palms, soles and scalp (off-label). “Voting: 5/7 strongly agree; 2/7 agree”</p> |
| Safety / Limitations |
| <p>12. HP/TAZ should not be applied to the face, intertriginous areas, and anogenital region, nor on sites with dermatitis/eczema. “Voting: 7/7 strongly agree”</p> <p>13. HP/TAZ is contraindicated in women who are pregnant or trying to conceive, as it may cause fetal harm. “Voting: 7/7 strongly agree”</p> <p>14. Halobetasol propionate enhances the tolerability of tazarotene and tazarotene reduces the atrophic potential of halobetasol propionate. “Voting: 4/7 strongly agree; 2/7 agree; 1/7 neutral”</p> <p>15. Treatment with HP/TAZ is generally well tolerated. Local application site reactions such as irritation can occur but are typically mild. These adverse effects can be mitigated by avoiding application to unaffected skin, letting the product dry before putting clothes on, concomitant use of an emollient, and less frequent initial application with subsequent titration. “Voting: 4/7 strongly agree; 3/7 agree”</p> |
| Efficacy |
| <p>16. Halobetasol propionate (a corticosteroid) and tazarotene (a retinoid) have synergistic mechanisms of action. When combined (HP/TAZ), efficacy is superior to that of the individual active components when used alone. “Voting: 7/7 strongly agree”</p> <p>17. HP/TAZ provides a reduction in redness, elevation/thickness and scaling as well as body surface area (BSA) involvement and supports treatment goals of achieving clear or almost clear skin. “Voting: 5/7 strongly agree; 2/7 agree”</p> <p>18. HP/TAZ has demonstrated effective disease control, with rapid onset of action and sustained improvement after treatment cessation, with some patients experiencing extended disease control beyond three months post-treatment. “Voting: 3/7 strongly agree; 3/7 agree; 1/7 neutral”</p> |
| Convenience / Acceptability / Accessibility |
| <p>19. The vehicle of HP/TAZ is aesthetically pleasing, hydrating, easily spreadable and rubs in quickly. “Voting Outcomes: 7/7 strongly agree”</p> <p>20. The once-daily fixed-formulation HP/TAZ, with its simultaneous delivery of two active components, may improve adherence by simplifying the treatment regimen. “Voting: 5/7 strongly agree; 2/7 agree”</p> |

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• Canadian Psoriasis Guidelines Committee, Canadian Guidelines for the Management of Plaque Psoriasis, June 2009;
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