NIHR | Innovation Observatory

Newcastle University

Health Technology Briefing
May 2026

IDP-126 for treating acne vulgaris

Company/Developer	Bausch Health

☒ New Active Substance ☐ Significant Licence Extension (SLE)

NIHRIO ID: 27146	NICE ID: Not available	UKPS ID: Not available

Licensing and Market Availability Plans

Currently in phase II/III clinical development.

Summary

Acne vulgaris is a common skin condition where the skin pores become clogged with oil and dead skin cells. Pore blockages produce blackheads, whiteheads, and other types of pimples and possible scarring. Pimples are pus-filled, sometimes painful, bumps on the skin. It primarily affects the face, upper part of the chest, and back. The causes of acne vulgaris include increased sebum production (of which the androgen hormone (hormones that drive masculine characteristics) can be the cause) and possible infection of the clogged pore amongst others. Acne occurs more often in adolescents and appears to be heritable. Possible triggers of acne flare-ups include hormonal factors, stress, diet, smoking, cosmetics, and some medicines. Current treatment of moderate to severe acne is a combination of topical treatments, or antibiotic tablets combined with topical treatments. These treatment regimens can have poor adherence due to complex complicated treatment regimens, poor efficacy and side effects.

IDP-126 is a triple-combination gel that is applied topically (to the skin). It combines clindamycin phosphate, benzoyl peroxide, and adapalene (all of which are currently used as separate acne treatments) into a single formulation. Clindamycin phosphate is antibacterial which counters bacteria that contribute to acne. Benzoyl peroxide has bactericidal (bacteria-killing) and keratolytic (breaks down dead skin cell build-up) effects. Adapalene affects skin cell build-up and inflammation. The combination of IDP-126 could improve treatment adherence due to simpler administration. If licensed, IDP-126 may offer an additional treatment option for treating acne vulgaris.

This briefing reflects the evidence available at the time of writing and a limited literature search. It is not intended to be a definitive statement on the safety, efficacy or effectiveness of the health technology covered and should not be used for commercial purposes or commissioning without additional information. A version of the briefing was sent to the company for a factual accuracy check. The company was unavailable to comment.

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Proposed Indication

Treatment of moderate or severe acne vulgaris.[1-4]

Technology

Description

IDP-126 (Cabtreo, Clindamycin phosphate 1.2%/benzoyl peroxide 3.1%/adapalene 0.15%), is a novel triple-combination gel, combining clindamycin phosphate, benzoyl peroxide, and adapalene into a single formulation.[5,6] Clindamycin is a lincosamide antibacterial, which binds to the 50S ribosomal subunits of susceptible bacteria and prevents elongation of peptide chains by interfering with peptidyl transfer, thereby suppressing bacterial protein synthesis. Benzoyl peroxide is an oxidising agent with bactericidal and keratolytic effects, but the precise mechanism of action is unknown. Adapalene binds to specific retinoic acid nuclear receptors but does not bind to cytosolic receptor protein. Biochemical and pharmacological profile studies have demonstrated that adapalene is a modulator of cellular differentiation, keratinisation and inflammatory processes. However, the significance of these findings with regard to the mechanism of action of adapalene for the treatment of acne is unknown. [7]

IDP-126 is currently in development for the treatment of moderate or severe acne vulgaris in patients aged 9 years and older. In phase III clinical trials (NCT04214652; NCT04214639) IDP-126 gel was applied topically to the face once daily for 12 weeks.[1,2]

Key Innovation

Acne vulgaris can be treated with topical combination therapies which have been shown to be more effective than oral medications or topical monotherapies. However, adherence challenges may arise when patients are prescribed complex multi-medication regimens.[6] Perceptions of poor efficacy, side effects, and complicated treatment regimens contribute to poor adherence to acne treatments, particularly among patients under 18 years of age. Efficacy, tolerability, and adherence to treatment with topical therapies may be improved by delivering them in fixed-combination formulations utilising enhanced vehicles, such as IDP-126.[8]

If licensed IDP-126 may offer an additional treatment option in treating moderate or severe acne vulgaris in adolescents and adults.

Regulatory & Development Status

IDP-126 does not currently have Marketing Authorisation in the EU/UK for any indication.

IDP-126 is not in phase II/III clinical development for any other indication.

Patient Group

Disease Area and Clinical Need

Acne vulgaris is a chronic inflammatory skin condition affecting mainly areas with the greatest density of pilosebaceous units, including the face (99% of cases), back (60% of cases), and chest (15% of cases). Acne is characterised by blockage and inflammation of the pilosebaceous unit (the hair follicle, hair shaft, and sebaceous gland).[9] A spectrum of lesions may be present, including non-inflammatory open and closed comedones (blackheads and whiteheads, respectively) and inflammatory papules, pustules, nodules, and cysts.[10] The pathogenesis of acne is thought to involve several processes, including the formation of

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follicular plugs (comedones), androgen-induced seborrhoea (increased sebum production) within the sebaceous follicles, the proliferation of bacteria (such as *Cutibacterium acnes*) within sebum in hair follicles, and inflammation of the pilosebaceous unit.[9,11] Acne severity is generally classified as mild, moderate, or severe. Mild acne consists mainly of whiteheads and blackheads, with a few papules and pustules. Moderate acne involves more widespread whiteheads and blackheads, along with numerous papules and pustules. Severe acne is marked by many large, painful papules, pustules, nodules, or cysts, and may lead to scarring.[12] Risk factors include genetic factors, endocrine disorders, stress, diet, smoking, insulin resistance, oil-based cosmetics, and certain medications.[13,14] The presence of acne can negatively affect quality of life, self-esteem, and mood in adolescents. Acne is associated with an increased incidence of anxiety, depression, and suicidal ideation.[15]

Acne is very common in adolescents and younger adults. About 95% of people aged 11 to 30 are affected by acne to some extent. Acne is most common in girls from the ages of 14 to 17 and in boys from the ages of 16 to 19. Acne often disappears when a person is in their mid-20s, but in some cases, can continue into adult life. About 3% of adults have acne over the age of 35.[14] In the United Kingdom, acne accounts for more than 3.5 million annual visits to general practitioners.[10] In England, in 2024-2025, there were 130 finished consultant episodes (FCE) for acne vulgaris (ICD-10 code L70.0) which resulted in 102 admissions and 66 FCE bed days.[16]

Recommended Treatment Options

The National Institute of Health and Care Excellence (NICE) has the following recommendations for the treatment of acne vulgaris:[17]

- a fixed combination of topical adapalene with topical benzoyl peroxide for any acne severity
- a fixed combination of topical tretinoin with topical clindamycin for any acne severity
- a fixed combination of topical benzoyl peroxide with topical clindamycin for mild to moderate acne
- a fixed combination of topical adapalene with topical benzoyl peroxide, plus either oral lymecycline or oral doxycycline for moderate to severe acne
- topical azelaic acid, plus either oral lymecycline or oral doxycycline for moderate to severe acne
- trimethoprim or an oral macrolide, for people who cannot tolerate or have contraindications to oral lymecycline or oral doxycycline

Clinical Trial Information

Trial	NCT04214652; A Phase 3, Multicenter, Randomized, Double-Blind, Vehicle Controlled, Parallel-Group, Clinical Study Comparing the Efficacy and Safety of IDP-126 Gel in the Treatment of Acne Vulgaris **Phase III –** Completed **Location(s):** USA and Canada **Study completion date:** March 2021
Trial Design	Randomised, parallel assignment, triple masked
Population	N=180 (actual); subjects with acne vulgaris with an Evaluator's Global Severity Score (EGSS) of 3 (moderate) or 4 (severe); aged 9 years and older.
Intervention(s)	IDP-126 gel applied topically to the face once daily for 12 weeks
Comparator(s)	Matched placebo
Outcome(s)	Primary outcomes [Time frame: 12 weeks]:

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	• Absolute change from baseline to week 12 in inflammatory lesion counts • Absolute change from baseline to week 12 in non-inflammatory lesion counts • Percentage of participants with success on the EGSS, defined as at least a two grade reduction and clear (0) or almost clear (1) See trial record for full list of other outcomes
Results (efficacy)	See trial record
Results (safety)	See trial record

Trial	NCT04214639; A Phase 3, Multicenter, Randomized, Double-Blind, Vehicle Controlled, Parallel-Group, Clinical Study Comparing the Efficacy and Safety of IDP-126 Gel in the Treatment of Acne Vulgaris **Phase III –** Completed **Location(s):** USA and Canada **Study completion date:** January 2021
Trial Design	Randomised, parallel assignment, triple masked
Population	N=183 (actual); subjects with acne vulgaris with an EGSS of 3 (moderate) or 4 (severe); aged 9 years and older
Intervention(s)	IDP-126 gel applied topically to the face once daily for 12 weeks
Comparator(s)	Matched placebo
Outcome(s)	Primary outcomes [Time frame: 12 weeks]: • Absolute change from baseline to week 12 in inflammatory lesion counts • Absolute change from baseline to week 12 in non-inflammatory lesion counts • Percentage of participants with success on the EGSS, defined as at least a two grade reduction and clear (0) or almost clear (1) See trial record for full list of other outcomes
Results (efficacy)	See trial record
Results (safety)	See trial record

Trial	NCT04892706, EudraCT 2021-000100-37; A Phase 2, Multicenter, Randomized, Double-Blind, Vehicle Controlled, Clinical Study to Compare the Safety and Efficacy of IDP-126 Gel to Epiduo® Forte Gel (0.3% Adapalene/2.5% BPO), in the Treatment of Acne Vulgaris **Phase II –** Completed **Location(s):** Belgium, USA and Canada **Study completion date:** September 2022
Trial Design	Randomised, parallel assignment, triple masked

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Population	N=686 (actual); subjects with acne vulgaris with an EGSS of 3 (moderate) or 4 (severe); aged 12 to 99 years
Intervention(s)	IDP-126 gel applied topically to the face once daily for 12 weeks
Comparator(s)	Matched placebo
Outcome(s)	Primary outcomes [Time frame: baseline to week 12]: • Absolute change from baseline to week 12 in lesion counts • Percentage of subjects who achieve at least a two-grade reduction from baseline and are "clear" or "almost clear" at week 12 in the EGSS See trial record for full list of other outcomes
Results (efficacy)	See trial record
Results (safety)	See trial record

Trial	NCT03170388; A Phase 2, Multicenter, Randomized, Double-Blind, Vehicle Controlled, Parallel-Group, Clinical Study Comparing the Efficacy and Safety of IDP-126 Gel in the Treatment of Acne Vulgaris **Phase II –** Completed **Location(s):** USA and Canada **Study completion date:** April 2019
Trial Design	Randomised, parallel assignment, triple masked
Population	N=741 (actual); subjects with acne vulgaris with an EGSS of 3 (moderate) or 4 (severe); aged 9 years to 99 years
Intervention(s)	IDP-126 gel application
Comparator(s)	Matched placebo
Outcome(s)	Primary outcomes [Time frame: baseline to week 12]: • Inflammatory lesion counts • Non-inflammatory lesion counts • Percentage of participants with success on the Evaluator's Global Severity Score, defined as at least a two grade reduction and clear (0) or almost clear (1) See trial record for full list of other outcomes
Results (efficacy)	See trial record
Results (safety)	See trial record

Estimated Cost

The cost of IDP-126 is not yet known.

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Relevant Guidance

NICE Guidance

- NICE guideline. Acne vulgaris: management (NG198). June 2021. Last updated December 2023.

NHS England (Policy/Commissioning) Guidance

- NHS England. Specialised Dermatology Services (Adults and Children). Service Specification (240501S). August 2024.

Other Guidance

- NHS Dorset Integrated Medicines Optimisation Committee. Acne Vulgaris - Primary Care Treatment Pathway. 2025.[18]
- Primary Care Dermatology Society. Guideline on acne vulgaris. 2024.[19]
- American Academy of Dermatology. Guidelines of care for the management of acne vulgaris. 2024.[20]

Additional Information

Bausch Health did not enter information about this technology onto the UK PharmaScan database; the primary source of information for UK horizon scanning organisations on new medicines in development. As a result, the NIHR Innovation Observatory has had to obtain data from other sources. UK PharmaScan is an essential tool to support effective NHS forward planning; allowing more effective decision making and faster uptake of innovative new medicines for patients who could benefit. We urge pharmaceutical companies to use UK PharmaScan so that we can be assured of up-to-date, accurate and comprehensive information on new medicines.

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