

Indiana Medicaid Therapeutics Committee Therapeutic Class Review Summary

Therapeutic Class:

Acne Agents

Overview:

Acne vulgaris is a common condition that affects nearly all adolescents and adults at some time in their lives. Prevalence rates are approximately as high as 75% in teenagers and young adults.¹³ Although overall health is not impaired, acne can produce cutaneous and emotional scars.¹² This disease is limited to pilosebaceous follicles of the head and upper trunk because the sebaceous glands in these regions are particularly active. Acne has a complex etiology involving abnormal keratinization, hormonal function, bacterial growth, and immune hypersensitivity.

There are several therapeutic options approved for the treatment of acne vulgaris in the United States. The pathophysiological goal of acne treatment includes the normalization of follicular keratinization, the reduction of interfollicular *Propionibacterium acnes*, the reduction of inflammation, and the reduction of sebaceous gland activity.^{14,16} Antibiotics and retinoids are used to treat acne vulgaris both topically and systemically. Topical therapy is recommended for mild-to-moderate non-inflammatory acne. Systemic therapy is reserved for moderate-to-severe acne that does not respond to topical therapy and for acne with high scarring potential.

Topical antibiotics used in the treatment of acne include benzoyl peroxide, clindamycin, erythromycin, and sodium sulfacetamide. The primary mechanism of action of these agents is the anti-*P. acnes* effect; although they also have some anticomedogenic effect (particularly benzoyl peroxide).²³ Topical antibiotics are often used in combination (eg, benzoyl peroxide/clindamycin, benzoyl peroxide/erythromycin). Combination products appear to be more effective without increasing adverse effects, mostly skin irritation. In theory, the addition of benzoyl peroxide may minimize antibiotic resistance to the other agent. Oral antibiotics used include doxycycline and minocycline.

Topical retinoids, such as adapalene, azelaic acid, and tretinoin, have proven to be highly effective treatments for acne vulgaris. Ziana™, a topical combination of tretinoin and clindamycin, is an additional alternative. Adapalene is a retinoid with potent anti-inflammatory and comedolytic properties. Azelaic acid apparently interferes with DNA synthesis in some of the bacteria associated with acne vulgaris. Tretinoin increases cell turnover in the follicular wall and decreases cohesiveness of cells, leading to extrusion of comedones and inhibition of the formation of new comedones.¹⁴ Tazarotene has an indication for acne in addition to its psoriasis indication (Tazarotene is included in the antipsoriatic review). The exact mechanism of action of tazarotene in acne is not defined. Clinical data suggest that some of the aforementioned treatments have similar efficacy and safety profiles, but some have a faster onset of action in the reduction of comedones. With various formulations and concentrations available, therapies may be individualized to specific patient needs while minimizing cutaneous irritation that is often observed with the use of these treatments.¹¹ Isotretinoin, an oral retinoid, is the treatment of choice for patients with severe nodular acne that has proven unresponsive to conventional

therapy, including systemic antibiotic therapy. Serious side effects, including birth defects, have been associated with isotretinoin. Therefore, women taking this medicine must use proper birth control.¹²

GENERIC NAME	TRADE NAME	MANUFACTURER	GENERIC
Adapalene	Differin [®]	Galderma	N
Azelaic Acid	Azelex [®]	Allergan	N
Benzoyl Peroxide/ Clindamycin	BenzaClin [®] , Duac [™]	Dermik, Stiefel	N
Clindamycin/Tretinoin	Ziana [™]	Medicis	N
Isotretinoin (10mg, 20mg, 40 mg)	Accutane [®] , Amnesteem [™] Claravis [®] , Sotret [®]	Various	Y
Isotretinoin (30 mg)	Claravis [®] , Sotret [®]	Barr, Ranbaxy	N
Sodium Sulfacetamide	Klaron [®]	Dermik	Y
Tretinoin	Retin-A [®] , Atralin [™] , Avita [®] , Altinac [®]	Various	Y

Notes: Tretinoin 10-mg capsules (Vesanoid[®]), indicated to treat acute promyelocytic leukemia (APL), are not discussed in this review. Tazarotene (Tazorac[®]), which is used to treat both acne and psoriasis, is discussed in the Antipsoriatic Therapeutic Class Review. Oral contraceptives used to treat acne are discussed in the Contraceptives Therapeutic Class Review.

Summary:

Selection of an acne vulgaris agent for the preferred drug list should be based on the overall efficacy and safety; including the ability of the medication to reduce sebum production, reduce *Propionibacterium acnes*, and normalize the shedding of the skin. In general, acne does not impact overall health, but it can produce cutaneous and psychosocial scars.¹² Ziana[™], a topical combination of both tretinoin and clindamycin, is an alternative treatment option for this condition. Sodium sulfacetamide, tretinoin, and isotretinoin are generically available and should be considered for inclusion on the preferred drug list.