



ZYCLARA
(imiquimod)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Zyclara (imiquimod) cream is used topically for actinic keratosis and external genital and perianal warts. Actinic keratosis (AK), also called solar keratosis, which is a chronic (long-term) condition of the skin caused by a chemical reaction to ultraviolet (UV) rays. Actinic keratosis can be linked to the development of skin cancer. External genital and perianal warts, also called condyloma acuminata (EGW), are caused by a virus known as human papillomavirus (HPV), and spread through sexual contact. Genital warts rarely cause health problems, but local symptoms of pain and itching may occur (1).

Regulatory Status

FDA-approved indications: Zyclara cream, 2.5% and 3.75% are indicated for the topical treatment of clinically typical, visible or palpable actinic keratosis (AK) of the full face or balding scalp in immunocompetent adults. Zyclara cream, 3.75% is also indicated for the topical treatment of external genital and perianal warts/condyloma acuminata (EGW) in patients 12 years and older (1).

Limitations of Use:

Efficacy of imiquimod cream was not demonstrated for molluscum contagiosum in children 2 to 12 years of age (1).

Summary

Zyclara (imiquimod) cream is a prescription medicine used topically for actinic keratosis and external genital and perianal warts. Actinic keratosis (AK) is a chronic (long-term) condition of the skin and can be linked to the development of skin cancer. External genital and perianal warts, also called condyloma acuminata (EGW), are caused by a virus known as human papillomavirus (HPV), and spread through sexual contact. Genital warts rarely cause health problems, but local symptoms of pain and itching may occur. Efficacy of imiquimod cream was not demonstrated for molluscum contagiosum in children 2 to 12 years of age (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Zyclara while maintaining optimal therapeutic outcomes.

References



**BlueCross
BlueShield**

Federal Employee Program.

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1. Zyclara [package Insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC.
February 2018.