RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Aldara cream is used for the treatment of actinic keratosis, external genital and perianal warts, and primary superficial basal cell carcinoma. 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. Superficial basal cell carcinoma (sBCC) is the most common form of skin cancer. It usually develops on skin that gets the most sun exposure such as on the backs of hands, on the head, and neck. 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 indication: Aldara cream is indicated for the topical treatment of: (1)
   1. Clinically typical, nonhyperkeratotic, nonhypertrophic actinic keratoses (AK) on the face or scalp in immunocompetent adults.
   2. Biopsy-confirmed, primary superficial basal cell carcinoma (sBCC) in immunocompetent adults; maximum tumor diameter of 2.0 cm on trunk, neck, or extremities (excluding hands and feet), only when surgical methods are medically less appropriate and patient follow-up can be reasonably assured.
   3. External genital and perianal warts/condyloma acuminata in patients 12 years old or older

Warning and precautions that should be discussed with the patient on Aldara therapy include intense local inflammatory reactions at application site which can lead to severe vulvar swelling. Severe vulvar swelling can lead to urinary retention (1).

Summary
Aldara is a prescription medicine used on the skin for actinic keratosis, external genital and perianal warts, and superficial basal cell carcinoma. Actinic keratosis (AK) is a chronic (long-term) condition of the skin and can be linked to the development of skin cancer. Superficial basal cell carcinoma is cancer of the skin caused by excessive sun exposure. 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).
Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Aldara while maintaining optimal therapeutic outcomes.

References