OVERVIEW
These topical products: Carac (fluorouracil 0.5% cream), fluorouracil 0.5% cream, fluorouracil 5% cream (Efudex, generics), fluorouracil 2% solution, fluorouracil 5% solution, Zyclara (imiquimod 2.5% cream, imiquimod 3.75% cream), imiquimod 5% cream (Aldara, generics), and Picato (ingenol mebutate 0.015% gel, ingenol mebutate 0.05% gel) are all indicated for the treatment of actinic keratosis (AK). Imiquimod 5% cream (Aldara, generics) and Zyclara (only the 3.75% strength) are also indicated for the treatment of external genital and perianal warts/condyloma cuminata in patients ≥ 12 years of age. Imiquimod 5% cream, fluorouracil 5% cream (Efudex, generics), and fluorouracil 5% solution are also indicated for the treatment of superficial basal cell carcinoma in certain patients.

Actinic keratosis (AK) is a common dermatologic skin condition and affects an estimated 58 million people in the US. AKs (also known as solar keratoses) are discrete, premalignant, intraepidermal lesions that appear on chronically sun-exposed areas (face, scalp, lips, forearms, and hands) of fair-skinned, middle-aged, and older individuals. Cumulative exposure to ultraviolet (UV) radiation from sunlight is considered the leading cause of AK.

POLICY STATEMENT
A preferred step therapy program has been developed to encourage the use of a Step 1 product prior to the use of a Step 2 product. If the preferred step therapy rule is not met for a Step 2 agent at the point of service, coverage will be determined by the preferred step therapy criteria below.

**Step 1:** Carac 0.5% cream, fluorouracil 2% solution, fluorouracil 5% solution, fluorouracil 5% cream, imiquimod 5% cream, Picato 0.015% gel, Picato 0.05% gel

**Step 2:** Aldara 5% cream, Efudex 5% cream, fluorouracil 0.5% cream, Zyclara 2.5% cream, Zyclara 3.75% cream

**Criteria**
1. If the patient has tried one Step 1 product, then authorization for a Step 2 product may be given.
2. No other exceptions are recommended.

**Approval Duration**
Approval = 365 days (1 year)
REFERENCES

- Aldara® cream [prescribing information]. Bridgewater, NJ. Valeant; August 2014.
- Efudex® topical solution and cream [prescribing information]. Bridgewater, NJ. Valeant; February 2016.
- Fluoroplex® cream [prescribing information]. West Chester, PA. Aqua Pharmaceuticals; March 2012.
- Fluorouracil 0.5% cream [prescribing information]. Randolph, NJ. Spear Dermatology Products; November 2012.
- Solaraze® Gel [prescribing information]. Melville, NY: PharmaDerm, a division of Fougera Pharmaceuticals; April 2016.