Topical Therapies for Actinic Keratosis

Goal(s):

- To ensure appropriate drug use and restrict to indications supported by medical literature. Allow case-by-case review for members covered under the EPSDT program.

Length of Authorization:

- Up to 3 months

Requires PA:

- Non-preferred agents for pharmacy claims
- Aminolevulinic ointment for provider administered claims

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Table 1. Topical Medications FDA-Approved in Actinic Keratosis and Other Indications

Generic Drug Name (BRAND NAME)	Strength/ Formulation	FDA-Approved Indications in Adults	Patient or Health Care Provider Administered	Dosing Guidance
5-fluorouracil (TOLAK, EFUDEX)	0.5% cream 4% cream 5% cream 2% solution 5% solution	• Actinic Keratosis • Basal Cell Carcinoma (5% cream or solution)	Patient	Maximum duration of therapy: 2 months Actinic Keratosis: • Fluorouracil 0.5% and 4% cream: Apply once daily up to 4 weeks. • Fluorouracil 1% cream: Apply twice daily for an average of 2-6 weeks. • Fluorouracil 5% cream: Apply twice daily for an average of 2-4 weeks. • Fluorouracil 2% and 5% solution: Apply twice daily for an average of 2-4 weeks. Basal Cell Carcinoma: • Fluorouracil 5% cream or solution: Apply twice daily for an average of 2-4 weeks.
Imiquimod (ALDARA, ZYCLARA)[1]	2.5% cream 3.75% cream 5% cream	• Actinic Keratosis in adults (2.5%, 3.75%, and 5% cream) • Basal Cell Carcinoma in adults (5% cream only) • Genital and Perianal Warts (3.75% cream & 5% cream) approved in	Patient	Actinic Keratosis: • Imiquimod 2.5% and 3.75% cream: Apply at bedtime (remove in 8 hours) x 2 weeks, off for 2 weeks then repeat x 2 weeks. Apply up to 0.5 grams per application. • Imiquimod 5% cream: Apply once daily before bedtime 2 times per week for 16 weeks. Apply no more than 1 packet per application. Basal Cell Carcinoma: • Imiquimod 5% cream: Apply once daily before bedtime 5 times per week

		children and adolescents ≥ 12 years)		for 6 weeks. Amount of cream used is based on target tumor diameter. Genital Warts: • Imiquimod 3.75% cream: Apply once daily (remove in 8 hours) up to 8 weeks. Apply up to 0.25 grams per application. • Imiquimod 5% cream: Apply once daily before bedtime 3 times per week until total clearance or for a maximum of 16 weeks.
Diclofenac Sodium (SOLARAZE)	3% gel	• Actinic Keratosis	Patient	• Apply twice daily for 60 to 90 days.
Tirbanibulin (KLISYRI)	1% ointment	• Actinic Keratosis	Patient	• Apply once daily (max one single dose packet) x 5 consecutive days.
Aminolevulinic acid (AMELUZ, LEVULAN)	10% gel (red or blue light) 20% solution (red light)	• Actinic Keratosis prior to photodynamic therapy	Health Care Provider	• 10% gel: Apply a maximum of 6 grams (3 tubes) at one time. Retreat lesions that have not completely resolved 3 months after the initial treatment. • 20% gel: Apply one treatment and may repeat after 8 weeks.

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is this an FDA approved indication (see **Table 1**)?	**Yes**: Go to #3	**No:** Pass to RPh. Deny; medical appropriateness.
3. Has the patient tried a preferred agent and do they have a contraindication, intolerance, or failure with this therapy?	**Yes**: Go to #4	**No:** Pass to RPh. Deny; medical appropriateness.
4. Is the diagnosis funded by OHP?	**Yes:** Go to #5	**No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP. If eligible for EPSDT review: Go to #5.

Approval Criteria		
5. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc.)	**Yes:** Approve for up to 4 months based on dosing parameters in Table 1.	**No:** Pass to RPh. Deny; medical necessity.

P&T/DUR Review: 6/25 (DM)
Implementation: 8/1/25