Pharmacy Policy Bulletin: J-1102 Panretin gel (alitretinoin) – Commercial and Healthcare Reform	
Number: J-1102	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Other Managed Prior Authorization = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1102-007	**Original Date:** 04/07/2021
Effective Date: 02/14/2025	**Review Date:** 01/29/2025

Drugs Product(s):	• Panretin gel (alitretinoin)
FDA-Approved Indication(s):	• Topical treatment of cutaneous lesions in patients with AIDS-related Kaposi's sarcoma (KS).

Background:	• Panretin is an endogenous retinoid that binds to and activates retinoic acid receptors (RARs) and retinoid X receptors (RXRs) on the cell nucleus causing keratinocyte differentiation and blocking neo-angiogenesis and proliferation of Kaposi sarcoma cells in vitro.
	• KS is a disease characterized by the presence of cancer cells in the skin and/or mucous membranes. It is caused by infection with the Kaposi sarcoma-associated herpesvirus (KSHV), which affects less than 1% of the US population. Carriers of the virus are more likely to develop the disease if they have a weakened immune system.
	• NCCN Guidelines for KS state that symptomatic and/or cosmetically bothersome KS warrants initiating anti-retroviral therapy (ART). However, ART may trigger immune reconstitution inflammatory syndrome (IRIS) within 3–6 months, marked by significant lesion swelling, increased pain, and peripheral edema. In patients with limited cutaneous disease, KS-associated IRIS indicates the need for immediate systemic KS treatment. Even signs of past IRIS may justify earlier systemic KS therapy.
	• First line therapies for limited cutaneous lesions that are symptomatic and/or cosmetically bothersome include local therapies such as Panretin (alitretinoin) 0.1% gel or imiquimod 5% cream, radiation therapy, systemic therapy or clinical trial.
	• For individuals with advanced cutaneous, oral, visceral, or nodal disease:
	  ○ Panretin is not recommended
	  ○ If ineligible for systemic therapy, radiation therapy is recommended
	  ○ If eligible for systemic therapy, options are systemic therapy or a clinical trial

	○ ART should be continued for PWH • There is no experience to-date using Panretin gel with systemic anti-KS treatment. Panretin gel is not indicated when systemic anti-KS therapy is required (e.g., more than 10 new KS lesions in the prior month, symptomatic lymphedema, symptomatic pulmonary KS, or symptomatic visceral involvement). • Prescribing Considerations: ○ Women of child-bearing potential should be advised to avoid becoming pregnant while using Panretin. ○ Patients using Panretin should be advised to minimize exposure of treated areas to sunlight or ultraviolet light during use. ○ Avoid applying to mucosal surfaces and normal skin surrounding the lesion. Let the gel dry 3 to 5 minutes before covering with clothing. ○ Do not use occlusive dressings with Panretin gel.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Panretin gel may be approved when all of the following criteria are met **(A. through E.)**:

A. The member is 18 years of age or older.

B. Panretin gel is prescribed by or in consultation with a dermatologist, oncologist, or infectious disease specialist.

C. The member has a diagnosis of AIDS-related Kaposi's sarcoma (ICD-10: C46.0).

D. The member is using Panretin gel for the topical treatment of cutaneous lesions.

E. The member is not receiving systemic therapy for Kaposi sarcoma.

II. Reauthorization

When a benefit, reauthorization of Panretin gel may be approved when the following criterion is met **(A.)**:

A. The prescriber attests that the member has experienced positive clinical response to therapy.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

IV. Coverage of oncology drug(s) listed in this policy may be approved on a case-by-case basis per indications supported in the most current NCCN guidelines.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Panretin [package insert]. Fort Lauderdale, FL: Concordia Pharmaceuticals. December 2024.
2. Clinical Pharmacology On-line, Tampa, FL: Elsevier 2023. Accessed: January 7, 2025.
3. DRUGDEX System (Micromedex 2.0). Greenwood Village, CO: Truven Health Analytics; 2023. Accessed: January 7, 2025.
4. Kaposi Sarcoma. National Comprehensive Cancer Network (NCCN). Version 1.2025—November 1, 2024. Accessed: January 7, 2025.