Clinical Policy: Alitretinoin (Panretin)

Reference Number: CP.CPA.137
Effective Date: 11.16.16
Last Review Date: 11.19
Line of Business: Commercial

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Alitretinoin (Panretin®) is a retinoid.

FDA Approved Indication(s)

Panretin is indicated for the topical treatment of cutaneous lesions in patients with acquired immune deficiency syndrome (AIDS)-related Kaposi's sarcoma (KS).

Limitation(s) of use:

- 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).
- There is no experience to date using Panretin gel with systemic anti-KS treatment.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Panretin is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Cutaneous Lesions (must meet all)**:**

1. Diagnosis of cutaneous lesions associated with AIDS-related KS;
2. Age ≥ 18 years.

Approval duration: Length of Benefit

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

II. Continued Therapy

A. Cutaneous Lesions (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy.

Approval duration: Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
AIDS: acquired immune deficiency syndrome
FDA: Food and Drug Administration
KS: Kaposi's sarcoma

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): known hypersensitivity to retinoids or to any of the ingredients of the product
- Boxed warning(s): none reported

Appendix D: General Information
- There is insufficient evidence to support the use of Panretin in the treatment of T-cell lymphoma and classic KS.
- Panretin is topical, not systemic; therefore it cannot treat visceral KS nor prevent the development of new lesions where it has not been applied.
- Evidence of systemic disease includes: more than 10 new lesions in the prior month or greater than 25 total lesions, symptomatic lymphedema, symptomatic pulmonary KS, symptomatic visceral disease.
- A response may be seen as soon as 2 weeks after initiation of therapy, but some patients have required over 14 weeks to respond. In clinical trials, Panretin was applied for up to 96 weeks. It should be continued as long as the patient is deriving benefit.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Cutaneous lesions associated with AIDS-related KS	Apply topically to lesions BID. May increase to 3-4 times daily	Four applications per lesion/day

VI. Product Availability

Gel (60 g): 0.1%

VII. References

1. Panretin Prescribing Information. Woodcliff Lake, NJ. Eisai Inc. June 2018. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=13c5de6d-d266-4d83-99c4-072ef104e7ff. Accessed August 13, 2019.
2. National Comprehensive Cancer Network. AIDS-Related Kaposi Sarcoma Version 2.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/kaposi.pdf. Accessed August 13, 2019.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 13, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template. Minor changes to verbiage and grammar. References updated.	01.11.17	11.17
4Q 2018 annual review: no significant changes; age added; references reviewed and updated.	07.02.18	11.18
4Q 2019 annual review: no significant changes; references reviewed and updated.	08.13.19	11.19

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to

applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.