RXADVANCE
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Clinical Policy Title:	alitretinoin
Policy Number:	RxA.452
Drug(s) Applied:	Panretin®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Alitretinoin (Panretin®) is a retinoid. It 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.

Dosing Information

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

Dosage Forms

- Gel (60 g): 0.1%

Clinical Policy

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

I. Initial Approval Criteria

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

1. Diagnosis of cutaneous lesions associated with AIDS-related KS;
2. Age ≥ 18 years.
3. Prescriber is an Infectious Disease Specialist or HIV/AIDS specialist
4. There are fewer than 10 new KS lesions in the prior month
5. Member does not have symptomatic lymphedema
6. Member does not have symptomatic pulmonary KS
7. Member does not have symptomatic visceral involvement

Approval Duration:
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

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

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy.
3. Age ≥ 18 years
4. Medication is not taken with systemic anti-KS therapy

Approval Duration:
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

AIDS: acquired immune deficiency syndrome
FDA: Food and Drug Administration
KS: Kaposi's sarcoma

APPENDIX B: Therapeutic Alternatives

None

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - known hypersensitivity to retinoids or to any of the ingredients of the product

- Boxed Warning(s):
  - None

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.

References

1. Panretin® Prescribing Information. Woodcliff Lake, NJ. Eisai Inc. July 2019 . Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=13c5de6d-d266-4d83-99c4072ef104e7ff. Accessed June 15, 2020
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 June 15, 2020 .
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed June 15, 2020
4. Alitretinoin, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: http://online.lexi.com. Accessed June 15, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated: Clinical Policy Title was updated to "alitretinoin". Drug(s) Applied was updated to "Panretin®. Line of Business Policy Applies to was updated to "All". 2. Clinical policy was updated: Approval duration was updated for both Initial and Continued Approval Criteria; Age criteria was updated to ⩾ 18 years; Continued Approval was rephrased to "Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy"; Limit coverage to members without an indication for systemic anti-KS therapy. 3. References were updated	06/15/2020	09/14/2020