Clinical Policy Title:	alitretinoin
Policy Number:	RxA.452
Drug(s) Applied:	Panretin®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2021
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 twice daily. May increase to 3-4 times daily based on individual lesion tolerance	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. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

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. Prescribed by or in consultation with 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;
8. Application does not exceed 4 applications topically per lesion/day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has 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;
5. Application does not exceed 4 applications per lesion/day.

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
HIV: Human immunodeficiency virus
ART: antiretroviral therapy

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.

References

1. Panretin® Prescribing Information. Woodcliff Lake, NJ. Eisai Inc. July 2019. Available at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=13c5de6d-d266-4d83-99c4-072ef104e7ff&type=display . Accessed July 14, 2021.
2. National Comprehensive Cancer Network. AIDS-Related Kaposi Sarcoma Version 2.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/kaposi.pdf . Accessed July 14, 2021.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed July 14, 2021.
4. Alitretinoin, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: http://online.lexi.com. Accessed July 14, 2021.
5. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2021. Accessed with subscription at: http://www.clinicalkey.com. Accessed July 14, 2021.

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". 2. Drug(s) Applied was updated to "Panretin®. 3. Line of Business Policy Applies to was updated to "All". 4. 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. 5. References were updated.	06/15/2020	09/14/2020
Policy was reviewed: 1. Dosing Information dosing regimen was updated to include "…based on individual lesion tolerance". 2. Statement about provider sample ''The provision of provider samples does not guarantee coverage…" was added to Clinical Policy.	7/14/2021	9/14/2021

3. Initial Approval Criteria I.A.8 was updated to include “Application does not exceed 4 applications topically per lesion/day”. 4. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 5. Continued Therapy Approval Criteria II.A.5 was updated to include “Application does not exceed 4 applications per lesion/day”. 6. Appendix A was updated to include abbreviations HIV and ART. 7. References were reviewed and updated.		