RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	pexidartinib
Policy Number:	RxA.511
Drug(s) Applied:	Turalio®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

Pexidartinib (Turalio®) is a kinase inhibitor indicated for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
pexidartinib (Turalio®)	TGCT	400 mg PO BID on an empty stomach (at least one hour before or two hours after a meal or snack) until disease progression or unacceptable toxicity	800 mg/day

Dosage Forms

- Capsule: 200 mg

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. Tenosynovial Giant Cell Tumor (must meet all)**:**

1. Diagnosis of TGCT (also known as giant cell tumor of the tendon sheath [GCT-TS] or pigmentedvillonodular synovitis [PVNS]);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is associated with severe morbidity or functional limitations and is not amenable to improvement with surgery;
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 800 mg (4 capsules) per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-

label use (prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Tenosynovial Giant Cell Tumor (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. If request is for a dose increase, request meets one of the following (a or b): *
   a. New dose does not exceed 800 mg (4 capsules) per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
CSF1R: colony stimulating factor 1 Receptor
FDA: Food and Drug Administration
GCT-TS: giant cell tumor of the tendon sheath
PVNS: pigmented villonodular synovitis
TGCT: tenosynovial giant cell tumor

APPENDIX B: Therapeutic Alternatives

- Not applicable

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported

- Boxed Warning(s):
  - Hepatotoxicity
    - Turalio is available only through a restricted program called the Turalio Risk Evaluation and Mitigation Strategy (REMS) Program (additional information available at: www.TuralioREMS.com).
    - Turalio can cause serious and potentially fatal liver injury.
    - Monitor liver tests prior to initiation of Turalio and at specified intervals during treatment. Withhold and dose reduce or permanently discontinue Turalio based on severity of hepatotoxicity.

APPENDIX D: General Information

- Pexidartinib is a small molecule tyrosine kinase inhibitor that targets colony stimulating factor 1 receptor (CSF1R), KIT proto-oncogene receptor tyrosine kinase (KIT), and FMS-like tyrosine kinase 3 (FLT3) harboring an internal tandem duplication (ITD) mutation.

- Turalio may cause fetal harm. Advise patients of reproductive potential of the potential risk to a fetus and to use an effective non-hormonal method of contraception.

References

1. Turalio Prescribing Information. Basking Ridge, NJ: Daiichi Sankyo Inc.; April 2020. Available at: https://dsi.com/prescribing-information-portlet/getPIContent?productName=Turalio&inline=true. Accessed September 16, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed September 16, 2020.
3. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 2.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed September 16, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical Policy Title Table was updated. 2. Line of business policy applies was updated to All lines of business. 3. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 4. Initial Approval criteria: Commercial approval duration was updated from member's Length of Benefit to 6 months. 5. Continued Approval criteria: Commercial approval duration were updated to 12 months. 6. APPENDIX D: General Information was updated to include the risk during pregnancy. 7. References was reviewed and updated. 8. Updated indication: Pexidartinib (Turalio®) is a kinase inhibitor indicated for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery.	09/16/2020	12/07/2020