Clinical Policy: Pexidartinib (Turalio)

Reference Number: ERX.SPA.346
Effective Date: 12.01.19
Last Review Date: 11.21
Line of Business: Commercial, Medicaid

Revision Log

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

Description
Pexidartinib (Turalio™) is a tyrosine kinase inhibitor with strong selective activity against colony stimulating factor 1 receptor (CSF1R).

FDA Approved Indication(s)
Turalio is 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.

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Turalio is **medically necessary** when the following criteria are met:

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 pigmented villonodular 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. For brand Turalio requests, member must use generic pexidartinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
6. 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 – Length of Benefit
Medicaid – 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Turalio for a covered indication and has received this medication for at least 30 days;

2. Member is responding positively to therapy;
3. For brand Turalio requests, member must use generic pexidartinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
4. 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 guideline 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 – Length of Benefit
Medicaid – 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

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).

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
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 Reduce the dose of Turalio if used concomitantly with moderate/strong CYP3A inhibitors or UGT inhibitors	800 mg/day

VI. Product Availability

Capsule: 200 mg

VII. References

1. Turalio Prescribing Information. Basking Ridge, NJ: Daiichi Sankyo Inc.; April 2020. Available at: www.turalio.com. Accessed June 28, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed June 28, 2021.
3. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 2.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed June 28, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	09.03.19	11.19
4Q 2020 annual review: no significant changes; references reviewed and updated.	07.13.20	11.20
4Q 2021 annual review: no significant changes; added language requiring trial of generic equivalent, if available; references reviewed and updated.	06.28.21	11.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.