Clinical Policy Title:	pexidartinib
Policy Number:	RxA.511
Drug(s) Applied:	Turalio®
Original Policy Date:	03/06/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Tenosynovial Giant Cell Tumor (TGCT) (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. Disease is associated with severe morbidity or functional limitations and is not amenable to improvement with surgery.

Approval duration

All Lines of Business (except Medicare): 6 months

B. Histiocytic Neoplasms (off-label) (must meet all)**:**

1. Diagnosis of one of the following conditions (a, b or c) with colony stimulating factor 1 receptor (CSF1R) mutation:
   a. Langerhans cell histiocytosis (LCH);
   b. Erdheim-Chester disease (ECD);
   c. Rosai-Dorfman disease (RDD);
2. Request is used as a single agent for first-line or subsequent therapy.

Approval duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval duration

All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed August 28, 2024.
2. National Comprehensive Cancer Network. Histiocytic Neoplasms Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/histiocytic_neoplasms.pdf. Accessed August 28, 2024.

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. References was reviewed and updated. 7. 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
Policy was reviewed: 1. Initial Approval Approval I.B for Off label indication ”Histiocytic Neoplasms” was added. 2. Continued Therapy Approval II.A.1 was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance…”. 3. References were reviewed and updated.	9/21/2021	12/07/2021
Policy was reviewed: 1. Initial Approval Criteria I.A.2, I.B.2: Updated to add prescriber criteria hematologist. 2. References were reviewed and updated.	09/06/2022	10/19/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.5.a, I.B.5.a: Updated dosing criteria from Dose does not exceed 800 mg (4 capsules) per day to dose does not exceed 500 mg (4 capsules) per day. 2. Continued Therapy Approval Crtieria, II.A.3.a: Updated dosing criteria from Dose does not exceed 800 mg (4 capsules) per day to dose does not exceed 500 mg (4 capsules) per day. 3. References were reviewed and updated.	11/21/2022	01/17/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions.	08/28/2024	09/13/2024

3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.		