PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Turalio Prior Authorization Policy
- Turalio® (pexidartinib capsules – Daiichi Sankyo)

REVIEW DATE: 08/30/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Turalio, a kinase inhibitor, is indicated for the treatment of **symptomatic tenosynovial giant cell tumor** associated with severe morbidity or functional limitations and not amenable to improvement with surgery in adults.[1]

Guidelines

Turalio is discussed in guidelines from the National Comprehensive Cancer Network (NCCN):

- **Histiocytic Neoplasms**: NCCN guidelines (version 1.2023 – August 11, 2023) recommend Turalio as first-line or subsequent therapy for *CSF1R* mutation target as "Useful in Certain Circumstances", for Langerhans cell histiocytosis, Erdheim-Chester disease, and Rosai-Dorfman disease in various settings (category 2A).[2-3]
- **Soft Tissue Sarcoma:** NCCN guidelines (version 2.2023 – April 25, 2023), indicate that Turalio is the "preferred" single-agent therapy for the treatment of pigmented villonodular synovitis/tenosynovial giant cell tumor (category 1).[3-4]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Turalio. All approvals are provided for the duration noted below.

- **Turalio® (pexidartinib capsules – Daiichi Sankyo)**

is(are) covered as medically necessary when the following criteria is(are) met for fda-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1) **Tenosynovial Giant Cell Tumor (Pigmented Villonodular Synovitis).** Approve for 1 year if the patient meets the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** According to the prescriber, the tumor is not amenable to improvement with surgery.

Other Uses with Supportive Evidence

2) **Histiocytic Neoplasms.** Approve for 1 year if the patient meets the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has a colony stimulating factor 1 receptor (*CSF1R*) mutation; AND
   - **C)** Patient has one of the following (i, ii, or iii):
     - **i.** Langerhans cell histiocytosis; OR
     - **ii.** Erdheim-Chester disease; OR
     - **iii.** Rosai-Dorfman disease.

CONDITIONS NOT COVERED

- **Turalio® (pexidartinib capsules – Daiichi Sankyo)**

is(are) considered experimental, investigational or unproven for ANY other use(s).

REFERENCES

1. Turalio® capsules [prescribing information]. Basking Ridge, NJ: Daiichi Sankyo; October 2022.
2. The NCCN Histiocytic Neoplasms Clinical Practice Guidelines in Oncology (version 1.2023 – August 11, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed August 24, 2023.
3. The NCCN Drugs and Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed August 24, 2023. Search term: pexidartinib.
4. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 2.2023 – April 25, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed August 24, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	08/17/2022
Annual Revision	No criteria changes.	08/30/2023