Turalio (pexidartinib)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Turalio (pexidartinib) 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.

Compendial Uses

1. Pigmented Villonodular Synovitis (PVNS)
2. Histiocytic Neoplasms:
   a. Erdheim-Chester Disease (ECD)
   b. Langerhans Cell Histiocytosis (LCH)
   c. Rosai-Dorfman Disease (RDD)

POLICY

Documentation

Submission of the following information is necessary to initiate the prior authorization review: Documentation of the presence of colony stimulating factor 1 receptor (CSF1R) mutation (where applicable).

Criteria for Initial Approval

A. Symptomatic Tenosynovial Giant Cell Tumor

Authorization of 6 months may be granted when ALL of the following criteria are met:

1. Member must have documented Tenosynovial Giant Cell Tumor (TGCT)
2. Member is not a candidate for surgery
3. Member has severe morbidity or functional limitations
4. Member does not have active cancer
5. Member is at least 18 years of age

B. Pigmented Villonodular Synovitis

Authorization of 6 months may be granted when ALL of the following criteria are met:

1. Member must have documented Pigmented Villonodular Synovitis (PVNS)
2. Member is not a candidate for surgery
3. Member has severe morbidity or functional limitations
4. Member does not have active cancer
5. Member is at least 18 years of age

C. Histiocytic Neoplasms

Authorization of 6 months will be granted for any of the following histiocytic neoplasm subtypes as a single agent in members with a CSF1R mutation:

1. Symptomatic or relapsed/refractory Erdheim-Chester Disease (ECD)
2. Symptomatic or relapsed/refractory Rosai-Dorfman Disease
3. Langerhans Cell Histiocytosis (LCH)

Continuation of Therapy

A. Symptomatic Tenosynovial Giant Cell Tumor (TGCT)

Authorization of 12 months may be granted for all members who meet all initial criteria AND all of the following:

1. Member has achieved stabilization or improvement in ALL of the following:
    a. Range of motion
    b. Pain
    c. Physical function
2. Member does not have progressive disease as defined by Tumor Volume Score or RECIST 1.1 criteria (See Appendices)
3. Member has been assessed by MRI within the last 12 months.

B. Pigmented Villonodular Synovitis (PVNS)

Authorization of 12 months may be granted for all members who meet all initial criteria AND all of the following:

1. Member has achieved stabilization or improvement in ALL of the following:
    a. Range of motion
    b. Pain
    c. Physical function
2. Member does not have progressive disease as defined by Tumor Volume Score or RECIST 1.1 criteria (See Appendices)
3. Member has been assessed by MRI within the last 12 months.

C. Histiocytic Neoplasms

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Turalio (pexidartinib) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Medication	Standard Limit	FDA-Recommended dosing
Turalio 200 mg capsules	120 per 30 days	Initial dose: 400mg (two 200mg capsules) twice daily Dose adjustments due to adverse reactions: • First reduction: 200 mg in the morning and 400 mg in the evening • Second reduction: 200 mg twice daily

Appendices

Appendix A:

Tumor Volume Score*
Partial Response: defined as at least 50% decrease in tumor volume score from baseline
Progressive Disease: defined as at least 30% increase in tumor volume score from nadir

* Measured as percentage of entire synovium

Appendix B:

RECIST 1.1*
Complete Response: defined as disappearance of all target lesions
Partial Response: defined as at least 30% decrease in sum of diameters of target lesions, using baseline sum diameters as reference
Progressive Disease: defined as at least 20% increase in sum of diameters of target lesions, referencing smallest sum on study, and an absolute increase of at least 5 mm or the appearance of one or more new lesions
Stable Disease: defined as neither sufficient shrinkage to qualify for partial response nor sufficient increase to qualify for progressive disease, referencing smallest sum diameters on study

* Measured as sum of diameters of target lesions

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- N/A

REFERENCES

- Turalio [package insert]. Rasking Ridge, NJ: Daiichi Sankyo, Inc.; October 2021.
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- The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed February 16, 2022.
- Pigmented Villonodular Synovitis. American Academy of Orthopaedic Surgeons. Available at: https://orthoinfo.aaos.org/en/diseases--conditions/pigmented-villonodular-synovitis#:~:text=Pigmented%20villonodular%20synovitis%20(PVNS)%20is,other%20areas%20of%20the%20body. Accessed October 1, 2021.

*Some content reprinted from CVS Health

POLICY HISTORY

Policy #: 05.02.81
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