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 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)

POLICY

Criteria for Initial Approval

A.) Symptomatic Tenosynovial Giant Cell Tumor [1]
Authorization of 6 months may be granted when ALL of the following criteria are met:

1. Member must have documented Tenosynovial Giant Cell Tumor (TSGT)
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

Continuation of Therapy
Authorization of 12 months may be granted for allmembers 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.

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

Quantity Limits

The standard limit is designed to allow a quantity sufficient for the most common uses of the medication. If the member's plan allows a quantity limit exception review for the requested medication, coverage of an additional quantity may be provided up to the exception limit with prior authorization.

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

Measured as percentage of entire synovium

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

Appendix B:

RECIST 1.1

Measured as sum of diameters of target lesions

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

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.

REFERENCES

- Turalio [package insert]. Rasking Ridge, NJ: Daiichi Sankyo, Inc.; April 2020.
- Von Mehren M, Kane JM, Benjamin RS et al. NCCN Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma. 2020;2. Accessed September 10, 2020.
- 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 September 10, 2020.

*Some content reprinted from CVS Health

POLICY HISTORY

Policy #: 05.02.81
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