For healthcare decision-makers only.
Information to Consider for PIMJETMI® (pimicotinib) Utilization Management

Product Overview

PIMJETMI® (pimicotinib) is a colony-stimulating factor-1 receptor (CSF-1R) inhibitor indicated for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection may cause worsening functional limitations or severe morbidity.[1]

PIMJETMI was approved by the FDA on November 10, 2026.[2]

The Lancet published the Phase 3 trial results for MANEUVER, which evaluated the safety and efficacy of PIMJETMI in adult patients with TGCT.[3]

Disease Overview

TGCT is a rare, locally aggressive tumor that can infiltrate and damage bone, cartilage, and soft tissue.[4-7] As an often progressive disease, it may lead to joint destruction and loss of function affecting an otherwise healthy adult population who are generally diagnosed between 25 and 50 years of age.[7,8] Symptoms of TGCT include swelling, pain, and reduced range of motion and physical functioning.[9] TGCT has an estimated incidence of 43 per 1 million people,[8] with ~5 per 1 million people expected to be eligible for systemic therapy.[10-15]

Approval Criteria

Initial Authorization

- The patient is 18 years of age or older
- The patient has been diagnosed with TGCT
- The patient has symptomatic TGCT for which surgical resection may cause worsening functional limitations or severe morbidity

Duration of initial authorization approval: 12 months.

Potential Reauthorization Criteria

- Prescriber attests that the patient:
    - Demonstrates clinical benefit (eg, tumor response, symptom improvement, or functional improvement), AND
    - Does not show evidence of unacceptable toxicity

Reauthorization will be provided for 12 months.

Drug Class

Antineoplastic: Colony-Stimulating Factor-1 Receptor (CSF-1R) Inhibitor

Dosage Form

- Oral capsules: 25 mg
    - Should be swallowed whole with or without food

IMPORTANT SAFETY INFORMATION

WARNINGS & PRECAUTIONS

Hepatotoxicity:

- Cases of serious & fatal liver injury have occurred with the use of another kinase inhibitor that targets colony-stimulating factor-1 receptor (CSF-1R). Serious & fatal liver injury have not been observed with PIMJETMI.
- Elevated aspartate aminotransferase (AST) & alanine aminotransferase (ALT) can occur with PIMJETMI.
- Avoid PIMJETMI in patients with pre-existing active liver or biliary disease.
- Monitor liver function tests (including AST, ALT, alkaline phosphatase (ALP), gamma-glutamyl transferase (GGT) & total bilirubin), prior to initiation of PIMJETMI, monthly for the first 3 months then every 3 months for the first year of therapy & as clinically indicated thereafter. Withhold & reduce the dose, or permanently discontinue PIMJETMI based on the severity of the liver transaminase elevations.

Embryo-Fetal Toxicity:

- PIMJETMI can cause fetal harm when administered to pregnant women. Advise pregnant women on the potential risk to the fetus.
- Advise females of reproductive potential & males with female partners of reproductive potential to use effective contraception during treatment with PIMJETMI & for 2 weeks after the last dose.

Increased Serum Creatinine without Affecting Renal Function:

- Increases in serum creatinine can occur with the use of PIMJETMI. These increases in serum creatinine may not be associated with changes in renal function. Increases in creatinine reversed upon PIMJETMI discontinuation. During PIMJETMI treatment, use alternative measures that are not based on serum creatinine to assess renal function.

Adverse Reactions:

The most common (>20%) adverse reactions were pruritus, rash, face edema, periorbital edema, fatigue, nausea, headache, & peripheral edema.

The most common (>30%) lab abnormalities were creatine phosphokinase increased, lactate dehydrogenase increased, AST increased, lipase increased, cholesterol increased, amylase increased, & ALT increased.

Drug Interactions:

- Strong & Moderate CYP3A Inhibitors: Avoid concomitant use of strong & moderate CYP3A inhibitors with PIMJETMI. If concomitant use cannot be avoided, reduce the PIMJETMI dosage (see Dosage & Administration).
- Strong & Moderate CYP3A Inducers: Avoid concomitant use of strong & moderate CYP3A inducers with PIMJETMI. If concomitant use of a moderate CYP3A inducer cannot be avoided, increase the PIMJETMI dosage (see Dosage & Administration).

Lactation: Advise females not to breastfeed during treatment with PIMJETMI & for 2 weeks after the last dose.

Please click here for full Prescribing Information.

References: 1. PIMJETMI. Prescribing Information. EMD Serono, Inc. **2.** US Food and Drug Administration. FDA approves pimicotinib for symptomatic tenosynovial giant cell tumor. Accessed November 10, 2026. https://www.fda.gov/drugs/cancer-approvals/fda-approves-pimicotinib-symptomatic-tenosynovial-giant-cell-tumor **3.** Xu H, Niu X, Ravi V, et al. Pimicotinib versus placebo for tenosynovial giant cell tumour (MANEUVER): an international, randomised, placebo-controlled, phase 3 trial. *Lancet.* 2026;407(10533):1072-1083. **4.** Spierenburg G, van der Heijden L, van Langevelde K, et al. Tenosynovial giant cell tumors (TGCT): molecular biology, drug targets and non-surgical pharmacological approaches. *Expert Opin Ther Targets.* 2022;26(4):333-345. **5.** Tap WD, Healey JH. Role of colony-stimulating factor 1 in the neoplastic process of tenosynovial giant cell tumor. *Tumour Biol*. 2022;44(1):239-248. **6.** Chandra AA, Agarwal S, Donahue A, Handorf E, Abraham JA. Arthroscopic versus open management of diffuse-type tenosynovial giant cell tumor of the knee: a meta-analysis of retrospective cohort studies. *J Am Acad Orthop Surg Glob Res Rev*. 2021;4(12):e21.00217. **7.** Stacchiotti S, Dürr HR, Schaefer IM, et al. Best clinical management of tenosynovial giant cell tumour (TGCT): a consensus paper from the community of experts. *Cancer Treat Rev.* 2023;112:102491. **8.** National Organization for Rare Disorders. Tenosynovial giant cell tumor. Updated September 29, 2023. Accessed September 3, 2026. https://rarediseases.org/rare-diseases/tenosynovial-giant-cell-tumor/ **9.** Gelhorn HL, Tong S, McQuarrie K, et al. Patient-reported symptoms of tenosynovial giant cell tumors. *Clin Ther.* 2016;38(4):778-793. **10.** Ehrenstein V, Andersen SL, Qazi I, et al. Tenosynovial giant cell tumor: incidence, prevalence, patient characteristics, and recurrence. A registry-based cohort study in Denmark. *J Rheumatol.* 2017;44(10):1476-1483. **11.** Mastboom MJL, Verspoor FGM, Verschoor AJ, et al. Higher incidence rates than previously known in tenosynovial giant cell tumors. *Acta Orthop.* 2017;88(6):688-694. **12.** Mastboom MJL, Palmerini E, Verspoor FGM, et al. Surgical outcomes of patients with diffuse-type tenosynovial giant-cell tumours: an international, retrospective, cohort study. *Lancet Oncol.* 2019;20(6):877-886. **13.** Burton TM, Ye X, Parker ED, Bancroft T, Healey J. Burden of illness associated with tenosynovial giant cell tumors. *Clin Ther*. 2018;40(4):593-602.e1. **14.** Verspoor FGM, van der Geest ICM, Vegt E, Veth RPH, van der Graaf WT, Schreuder HWB. Pigmented villonodular synovitis: current concepts about diagnosis and management. *Future Oncol.* 2013;9(10):1515-1531. **15.** Bernthal NM, Healey JH, Palmerini E, et al. A prospective real-world study of the diffuse-type tenosynovial giant cell tumor patient journey: a 2-year observational analysis. *J Surg Oncol.* 2022;126(8):1520-1532.

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