SpringWorks CareConnections

844-CARES-55 (844-227-3755)
Monday – Friday, [8 AM – 8 PM] ET

Peer-to-Peer Review Checklist

You can also visit springworkstxcares.com/pimjetmi/hcp/resources

Scheduling a peer-to-peer review with the medical director at your patient's health plan may be useful when coverage for PIMJETMI® (pimicotinib) is denied under the plan's coverage policy. During the review, you will have the opportunity to explain your clinical rationale for prescribing PIMJETMI to your patient. This resource provides a checklist and relevant tips to help you prepare for and engage in a peer-to-peer discussion.

The information in this checklist does not guarantee that the health plan will accommodate a request for peer-to-peer review, or otherwise provide reimbursement, and it is not intended to be a substitute for your independent medical judgment. When completing any request, it is your responsibility as your patient's healthcare provider to adhere to the payor's specific requirements at that time. Please see the Indication and Important Safety Information on the next page.

How to Prepare for Your Peer-to-Peer Meeting

Follow the steps below to help you prepare:

- ☐ **Request to speak with a peer reviewer** within the same specialty
- ☐ **Confirm the date and time** of the call
- ☐ **Review the health plan's clinical policy** to determine if all the requirements have been met
- ☐ **Gather all the documentation submitted** with the initial prior authorization (PA) to the health plan:
  - ✓ Valid prescription for PIMJETMI
  - ✓ Letter of medical necessity
  - ✓ Supporting documentation, which may include a copy of chart notes with details about the patient's diagnosis, current clinical status, laboratory values, treatment history, etc, and any literature that was provided
  - ✓ Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment
- ☐ **If an appeal was pursued,** be sure to gather the denial letter(s) received from the health plan as well as your letter of appeal in response

What to Expect During Your Peer-to-Peer Discussion

Be prepared to discuss the following information:

- ☐ **Information about PIMJETMI:**
  - ✓ **PIMJETMI indication**
  - ✓ **Recommended dosage of PIMJETMI**
  - ✓ **National Drug Code (NDC)** 44087-6100-06[1] for dosage prescribed
  - ✓ **Why PIMJETMI is the appropriate treatment option** for your patient (eg, efficacy/safety profile
- ☐ **Literature supporting your decision** to prescribe PIMJETMI:
  - ✓ **Clinical trial publication for PIMJETMI** (MANEUVER Phase 3 safety and efficacy data)
  - ✓ **Peer-reviewed journal articles** (For the PIMJETMI Evidence Compendium, visit www.springworkstxcares.com/pimjetmi/hcp/resources)
  - ✓ **Clinical practice guidelines**
- ☐ **Next steps:**
  - ✓ **Confirm timing and approval** and note any required follow-up steps

If the peer-to-peer discussion does not resolve the denial, an appeal can be pursued.
For a sample letter of appeal, appeals checklist, and other access resources, visit
www.springworkstxcares.com/pimjetmi/hcp/resources

Pimjetmi® (pimicotinib) 25 mg hard capsules

Please see Important Safety Information on next page and click here for full Prescribing Information.

INDICATIONS & USAGE

PIMJETMI (pimicotinib) is indicated for treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection may cause worsening functional limitations or severe morbidity.

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.

Reference: 1. PIMJETMI. Prescribing Information. EMD Serono, Inc.

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SpringWorks CareConnections®

Pimjetmi® (pimicotinib) 25 mg hard capsules