Instructions for the iKnowMed™ Electronic Health Record (EHR) System to Update or Create Order Sets With TEPMETKO®

INDICATION

TEPMETKO is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (*MET*) exon 14 skipping alterations.

SELECT IMPORTANT SAFETY INFORMATION

TEPMETKO can cause **interstitial lung disease (ILD)/pneumonitis**, which can be fatal. Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis (eg, dyspnea, cough, fever). Immediately withhold TEPMETKO in patients with suspected ILD/pneumonitis and permanently discontinue if no other potential causes of ILD/pneumonitis are identified. ILD/pneumonitis occurred in 2% of patients treated with TEPMETKO, with one patient experiencing a Grade 3 or higher event; this event resulted in death.

Please see Important Safety Information on page 6.
Click for full Prescribing Information.

TEPMETKO® (tepotinib) 225 mg Tablets

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1. Background

This document is intended to provide medical groups with instructions to update metastatic non-small cell lung cancer (NSCLC) order sets with TEPMETKO® within the approved indication and consistent with the Prescribing Information. This document is not intended to provide any clinical advice or clinical recommendations, which are solely the responsibility of the healthcare professionals.

These instructions are specific to metastatic NSCLC and to the iKnowMed™ EHR system and are not appropriate for other conditions, treatments, therapeutic areas, or other EHR systems.

2. Considerations

The process outlined below is variable and not all steps will apply to every medical group. Any steps or settings below that are not part of a medical group's standard process should be excluded or modified accordingly. Any questions should be directed to the appropriate service provider. The medical group is solely responsible for implementing, testing, monitoring, and the ongoing operation of any EHR tools.

Please consult the most recent version of the TEPMETKO package insert for full medication details. The most recent version can be found at **https://www.emdserono.com/us-en/pi/tepmetko-pi.pdf**.

A new order set will be available once the optimization process is complete. If the original order set used to update or create the new order set includes TEPMETKO, confirm the original order set is retired or removed from the EHR production system according to the medical group's EHR governing principles.

3. iKnowMed Instructions

iKnowMed allows for treatment regimens to be updated by optimizing a treatment regimen. After the initial release of a treatment regimen, order sets may benefit from a clinical update. The optimization of regimens is a common process and provides an opportunity to account for treatment updates.

1. Access the Regimens Templates with admin credentials (Treatment Regimen Orders editor)
2. In the Regimen Search window, search by Diagnosis/Problem by entering "metastatic NSCLC" in the search field. Click the Search for Regimens button, and regimens matching the search terms will display. Select the desired regimen to update by copying it and renaming it
3. Adjust the Regimens Search Rules and Problems Associations if desired
4. Complete the Display Name as: "*TEPMETKO for metastatic NSCLC with METex14 skipping alterations*"
5. Add in the Reference Name as: "*TEPMETKO for metastatic NSCLC with METex14 skipping alterations*"
6. In the Regimen Comments, or Instructions to Provider field, enter:
   - A link to the PI *(https://www.emdserono.com/us-en/pi/tepmetko-pi.pdf)* for the most recent information regarding *Patient Selection for METex14 Skipping Alterations, Recommended Dosage, Administration to Patients Who Have Difficulty Swallowing Solids, Dose Modifications for Adverse Reactions (see Table 1), and Warnings and Precautions*

     TEPMETKO Prescribing Information:

     i. *See URL for additional TEPMETKO dosing and administration information (https://www.emdserono.com/us-en/pi/tepmetko-pi.pdf)*

     TEPMETKO Resources for Healthcare Providers (HCPs) and Patients:

     ii. *Treatment Guide, Patient Brochure, and Patient Savings Offers: See URL for additional TEPMETKO Resources for Healthcare Providers (HCPs) and Patients such as a Treatment Guide, Patient Brochure, and Patient Savings Offers (https://www.tepmetko.com/us-en/home.html)*
7. Add TEPMETKO to the Treatment Group by clicking the plus sign next to the Treatment Group
8. Click + Add Group and add a Treatment Group for TEPMETKO
9. In the Order Review tab, complete the Treatment Regimen and add:
   i. TEPMETKO: 450 mg orally once daily with food
   ii. Continue treatment until disease progression or unacceptable toxicity
10. Click Save to complete the new Treatment Regimen

The medical groups shall be solely responsible for implementation, testing, and monitoring of the instructions to ensure proper orientation in each medical group's EHR system.

After completing the TEPMETKO order set optimization process, a new TEPMETKO order set will be available. If the original order set used to update or create the new TEPMETKO order set included TEPMETKO, confirm the original order set is retired or removed from the EHR production system according to the medical group's EHR governing principles.

Capabilities, functionality, and setup (customization) for each individual EHR system vary. EMD Serono is not responsible for revising the implementation instructions it provides to any medical group.

While EMD Serono tests its implementation instructions on multiple EHR systems, the instructions are not guaranteed to work for all available EHR systems, and EMD Serono shall have no liability therefor.

While EHRs may assist providers in identifying appropriate patients for consideration of assessment and treatment, the decision and action should ultimately be made by a healthcare provider in consultation with the patient after a review of the patient's records to determine eligibility.

These instructions have not been designed and are not tools and/or solutions for meeting Advancing Care Information, and/or any other quality/accreditation requirement.

Reference to these EHRs is not intended to imply affiliation with or sponsorship of the EHR manufacturer and/or its affiliates.

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TEPMETKO can cause **hepatotoxicity**, which can be fatal. Monitor liver function tests (including alanine aminotransferase [ALT], aspartate aminotransferase [AST], and total bilirubin) prior to the start of TEPMETKO, every 2 weeks during the first 3 months of treatment, then once a month or as clinically indicated, with more frequent testing in patients who develop increased transaminases or total bilirubin. Based on the severity of the adverse reaction, withhold, dose reduce, or permanently discontinue TEPMETKO. Increased ALT/ increased AST occurred in 18% of patients treated with TEPMETKO. Grade 3 or 4 increased ALT/AST occurred in 4.7% of patients. A fatal adverse reaction of hepatic failure occurred in one patient (0.2%). The median time-to-onset of Grade 3 or higher increased ALT/AST was 47 days (range 1 to 262).

TEPMETKO can cause **pancreatic toxicity** in the form of elevations in amylase and lipase levels. Increased amylase and/or lipase occurred in 13% of patients, with Grade 3 and 4 increases occurring in 5% and 1.2% of patients, respectively. Monitor amylase and lipase levels at baseline and regularly during treatment with TEPMETKO and temporarily withhold, dose reduce, or permanently discontinue based on severity of the adverse event.

TEPMETKO can cause **embryo-fetal toxicity**. Based on findings in animal studies and its mechanism of action, TEPMETKO can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential or males with female partners of reproductive potential to use effective contraception during treatment with TEPMETKO and for one week after the last dose.

Avoid concomitant use of TEPMETKO with certain **P-gp substrates** where minimal concentration changes may lead to serious or life-threatening toxicities. If concomitant use is unavoidable, reduce the P-gp substrate dosage if recommended in its approved product labeling.

Fatal adverse reactions occurred in one patient (0.3%) due to pneumonitis, one patient (0.3%) due to hepatic failure, one patient (0.3%) due to dyspnea from fluid overload, one patient (0.3%) due to pneumonia, one patient (0.3%) due to sepsis, and one patient (0.3%) from unknown cause.

Serious adverse reactions occurred in 51% of patients who received TEPMETKO. Serious adverse reactions in >2% of patients included pleural effusion (6%), pneumonia (6%), edema (5%), general health deterioration (3.8%), dyspnea (3.5%), musculoskeletal pain (2.9%), and pulmonary embolism (2.2%).

The most common adverse reactions (≥20%) in patients who received TEPMETKO were edema (81%), nausea (31%), fatigue (30%), musculoskeletal pain (30%), diarrhea (29%), dyspnea (24%), rash (21%), and decreased appetite (21%).

Clinically relevant adverse reactions in <10% of patients who received TEPMETKO included ILD/pneumonitis, fever, dizziness, pruritus, and headache.

Selected laboratory abnormalities (≥20%) from baseline in patients receiving TEPMETKO in descending order were: decreased albumin (81%), increased creatinine (60%), decreased lymphocytes (57%), increased alkaline phosphatase (ALP) (52%), increased ALT (50%), increased AST (40%), decreased sodium (36%), decreased hemoglobin (31%), increased gamma-glutamyltransferase (GGT) (29%), increased potassium (26%), increased amylase (25%), decreased leukocytes (25%), decreased platelets (24%), and increased lipase (21%).

The most common Grade 3-4 laboratory abnormalities (≥2%) in descending order were: decreased lymphocytes (15%), decreased albumin (9%), decreased sodium (9%), increased GGT (6%), increased amylase (5%), increased lipase (5%), increased ALT (4.9%), increased AST (3.6%), and decreased hemoglobin (3.6%).

Please see the full Prescribing Information for TEPMETKO.

EMD SERONO

US-TEP-00611 09/24.

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