

Pemfexy[™] (pemetrexed) – New indication

- On December 19, 2022, <u>Eagle Pharmaceuticals announced</u> the <u>FDA approval</u> of <u>Pemfexy</u> (<u>pemetrexed</u>), in combination with <u>Keytruda[®]</u> (<u>pembrolizumab</u>) and platinum chemotherapy, for the initial treatment of patients with metastatic non-squamous non-small cell lung cancer (NSCLC), with no EGFR or ALK genomic tumor aberrations.
- Pemfexy is also approved:
 - In combination with cisplatin for the initial treatment of patients with locally advanced or metastatic, nonsquamous NSCLC
 - As a single agent for the maintenance treatment of patients with locally advanced or metastatic nonsquamous NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy
 - As a single agent for the treatment of patients with recurrent, metastatic non-squamous NSCLC after prior chemotherapy
 - In combination with cisplatin for the initial treatment of patients with malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery.
- The indications for Pemfexy now mirror another pemetrexed formulation, <u>Alimta[®]</u>. Generics are available for Alimta.
- The most common adverse reactions (≥ 20%) with Pemfexy use when administered in combination with Keytruda and platinum chemotherapy were fatigue/asthenia, nausea, constipation, diarrhea, decreased appetite, rash, vomiting, cough, dyspnea, and pyrexia.
- The recommended dose of Pemfexy, when administered with Keytruda and platinum chemotherapy for the initial treatment of metastatic non-squamous NSCLC, is 500 mg/m² as an intravenous infusion administered after Keytruda and prior to carboplatin or cisplatin on day 1 of each 21-day cycle for 4 cycles. Following completion of platinum-based therapy, treatment with Pemfexy with or without Keytruda is administered until disease progression or unacceptable toxicity.
 - Refer to the drug labels for Keytruda and for carboplatin or cisplatin for their dosing information.
 - Refer to the Pemfexy drug label for dosing for all its other indications.



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