Criteria for Nonformulary Use of Pemetrexed

VA Pharmacy Benefits Management Strategic Healthcare Group and Medical Advisory Panel

The following recommendations are based on current medical evidence and expert opinion from clinicians. The content of the document is dynamic and will be revised as new clinical data becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. The clinician should utilize this guidance and interpret it in the clinical context of individual patient situations

Refer to the National PBM Drug Monograph Pemetrexed (Alimta®) at http://www.pbm.va.gov/monograph/765rtwPemetrexedMono.pdf or http://vaww.pbm.va.gov/drugmonograph/765rtwPemetrexedMono.pdf for recommendations on dosing, precautions, and monitoring

Diagnosis A	**#1**
Malignant Pleural Mesothelioma that is not resectable	☐ Yes ☐ No *If Yes to #1, go to #3.* *If No to #1 patient is not eligible*
Diagnosis B	**#2**
Stage III or IV Non-Small-Cell Lung Cancer Following at least 1 prior chemotherapy for locally advanced or metastatic disease	☐ Yes ☐ No *If Yes to #2, go to #4* *If No to #2, patient is not eligible*
Exclusion Criteria A: Malignant Pleural Mesothelioma	**#3**
Patient with one of the following conditions: ❑ Note: Prior systemic chemotherapy for mesothelioma was an exclusion in clinical trials; individual patient situations may allow for use following prior chemotherapy ❑ Symptomatic or uncontrolled brain metastasis ❑ Karnofsky Performance Status <70 http://www2.mc.duke.edu/depts/hospital/9200bmt/Karnofsky.htm ❑ Eligible for surgical resection ❑ Creatinine clearance <45 ml/minute ❑ Inability to interrupt NSAID therapy in patients with mild to moderate renal insufficiency (creatinine clearance 45-79 ml/min) ❑ Inability to comply with folic acid and Vitamin B_{12} regimen ❑ Inability to comply with steroid pretreatment regimen	☐ Yes ☐ No *If Yes to #1 and No to all conditions in #3, patient is eligible for pemetrexed* with cisplatin*
Exclusion Criteria B: Non-Small-Cell Lung Cancer	**#4**
Patient with one of the following conditions: ❑ Prior pemetrexed ❑ ≥ Grade 3 Peripheral Neuropathy ❑ Creatinine clearance <45 ml/minute ❑ Uncontrolled pleural effusion *Use with caution after drainage of effusion/ascites* ❑ Symptomatic or uncontrolled brain metastases ❑ No prior first-line chemotherapy for advanced disease ❑ ECOG Performance Status >2 http://www.ecog.org/general/perf_stat.html ❑ Inability to comply with folic acid and Vitamin B_{12} regimen ❑ Inability to stop NSAID therapy in patients with mild to moderate renal insufficiency (creatinine clearance 45-79 ml/min)	☐ Yes (to any condition) ☐ No (to all conditions) *If Yes to #2 and No to all conditions in #4, patient is eligible to receive pemetrexed**
Discontinuation	**#5**
Mesothelioma: need for >3 dose reductions for hematologic toxicity, creatinine clearance sustained at <45 ml/minute, progressive disease (new lesions, reappearance of lesion, ≥50% increase in measurable lesion size, worsening of assessable [non-measurable] disease), or unacceptable toxicity Non-small cell lung cancer: disease progression (appearance of new lesions, 20% increase in sum of the longest diameter of target lesions for measurable lesions, worsening of non-measurable disease), unacceptable toxicity, creatinine clearance sustained at <45 ml/minute, >2 dose reductions for nadir blood counts or significant nonhematologic toxicity	☐ Yes ☐ No *If Yes to #5, pemetrexed therapy should be discontinued*

*Patients should avoid NSAIDS with short elimination half-lives for 2 days before, the day of, and 2 days after pemetrexed. Patients taking NSAIDS with long elimination half-lives should interrupt therapy for 5 days before, the day of, and for 2 days after pemetrexed.

Approved by Physician: Date/Time