

Title: *pemetrexed (Alimta)*

Origination: 07/28/10	Revised:	Annual Review: 12/15/11
------------------------------	-----------------	--------------------------------

Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Reference Statement

- Guidelines are compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Medication Summary

- Alimta (pemetrexed for injection) is a folate analog metabolic inhibitor that exerts its action by disrupting folate-dependent metabolic processes essential for cell replication. In vitro studies have shown that pemetrexed inhibits thymidylate synthase (TS), dihydrofolate reductase (DHFR), and glycinamide ribonucleotide formyltransferase (GARFT), which are folate-dependent enzymes involved in the de novo biosynthesis of thymidine and purine nucleotides.
- Once in the cell, pemetrexed is converted to polyglutamate forms by the enzyme folylpolyglutamate synthetase. The polyglutamate forms are retained in cells and are inhibitors of TS and GARFT. Polyglutamation is a time- and concentration-dependent process that occurs in tumor cells and, is thought to occur to a lesser extent, in normal tissues. Polyglutamated metabolites are thought to have an increased intracellular half-life resulting in prolonged drug action in malignant cells.
- Indications include: nonsquamous non-small cell lung cancer (combination with Cisplatin, or maintenance, or after prior chemotherapy), and mesothelioma.
- The recommended dose of Alimta is 500mg/m² administered as an IV infusion over 10 minutes on Day 1 of each 21-day cycle.

Eligibility Criteria

- Member must be eligible and have applicable benefit coverage (i.e., self-injectable rider) within the specified date(s) of service.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Exclusion Criteria

- Hypersensitivity to Alimta or any component of the product.

Title: pemetrexed (Alimta)

Procedure:

- 1.0 Request for *initial therapy* with Alimta for **Bladder Cancer** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying all of the following:
 - 1.1 Second line treatment of metastatic disease; **AND**
 - 1.2 Used as a single agent;
 - 1.3 If criteria are met, Alimta is approvable for up to six (6) months.
- 2.0 Request for *initial therapy* with Alimta for **Bladder Cancer-upper Genitourinary tumors** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying all of the following:
 - 2.1 For second line treatment of metastatic disease; **AND**
 - 2.2 Used as a single agent;
 - 2.3 If criteria are met, Alimta is approvable for up to six (6) months.
- 3.0 Request for *initial therapy* with Alimta for **Malignant pleural mesothelioma** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying all of the following:
 - 3.1 Used in combination with Cisplatin or Carboplatin;
 - 3.2 If criteria are met, Alimta is approvable for up to six (6) months.
- 4.0 Request for *initial therapy* with Alimta for **nonsquamous non-small cell lung cancer** requires documentation from the Member's medical records maintained by the requesting independent practitioner.
 - 4.1 Alimta is approvable for up to six (6) months.

Title: pemetrexed (Alimta)

Procedure, continued:

- 5.0 Request for *initial therapy* with Alimta for **thymic malignancies** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying all of the following:
- 5.1 For second line treatment of locally advanced unresectable disease; **AND**
 - 5.2 Used as a single agent;
 - 5.3 If criteria are met, Alimta is approvable for up to six (6) months;
- 6.0 Request for *initial therapy* with Alimta for **Ovarian Cancer** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying all of the following:
- 6.1 For relapsed or refractory disease; **AND**
 - 6.2 Used as a single agent;
 - 6.3 If criteria are met, Alimta is approvable for up to six (6) months.
- 7.0 Request for *initial therapy* with Alimta for **Cervical Cancer** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying all of the following:
- 7.1 Second line treatment of metastatic disease; **AND**
 - 7.2 Used as a single agent;
 - 7.3 If criteria are met, Alimta is approvable for up to six (6) months.
- 8.0 Request for *continuation therapy* with Alimta for **all above conditions** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying **tumor response**.

Title: pemetrexed (Alimta)

References:

1. Alimta Prescribing Information. Eli Lilly and Company. Indianapolis, IN. Rev 12/2009.
2. Facts and Comparisons 4.0, St. Louis, MO. Walters Kluwer Health URL: www.factsandcomparisons.com. Updated 2010.
3. National Comprehensive Cancer Network, Inc. (NCCN) Practice Guidelines in Oncology Version 2.2010, March 2010. Available at: www.nccn.org/professionals/physician_gls/f_guidelines.asp

Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.