Chemotherapy: Pemetrexed Drugs (NSCLC) Step Therapy

Pemetrexed: Pemfexy J9304 is non-preferred. The preferred products are Hospira J9294, Accord J9296, Sandz J9297, Alimta J9305, Teva J9314.

Prior Authorization Request

Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ **New Start or Initial Request: (Clinical documentation required for all requests)**

☐ Patient has a diagnosis of malignant mesothelioma; AND

☐ Patient is using in combination with cisplatin or carboplatin;

OR

☐ Patient is using as a first-line therapy in combination with cisplatin or carboplatin AND bevacizumab (or bevacizumab biosimilar); AND

☐ Patient has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2; AND

☐ Patient does not have a history of hemoptysis or thrombosis; AND

☐ Disease presentation is unresectable;

OR

☐ Patient is using as single agent for subsequent therapy; AND

☐ Pemetrexed was not administered as first-line; OR

☐ Pemetrexed was used as first-line with good sustained response;

☐ Patient is using as single agent for first line systemic therapy;

OR

☐ Patient has a diagnosis of recurrent, locally advanced, or metastatic non-squamous, non-small cell lung cancer (NSCLC); AND

- ☐ Patient is using as a single agent after prior chemotherapy; OR
- ☐ Patient is using as a first-line therapy in combination with platinum based chemotherapy with or without bevacizumab (or bevacizumab biosimilar) ; OR
- ☐ Patient is using as second-line therapy (first-line chemotherapy) in combination with platinum-based chemotherapy with or without bevacizumab (or bevacizumab biosimilar) if tyrosine-kinase inhibitor (TKI/anaplastic lymphoma kinase (ALK) targeted agent was given as first-line therapy ; OR
- ☐ Patient is using for maintenance therapy when disease has not progressed following four cycles of platinum-based, first-line therapy; OR
- ☐ Patient is using in combination with pembrolizumab (Keytruda) and platinum chemotherapy for initial treatment and without presence of actionable molecular markers; OR
- ☐ Patient is using as continuous maintenance therapy until disease progression, if given first-line as part of Keytruda (pembrolizumab)/platinum chemotherapy/and pemetrexed regimen; OR
- ☐ Patient is using in combination with cemiplimab and platinum chemotherapy; OR
- ☐ Patient is using in combination with tremelimumab, durvalumab, and platinum chemotherapy; OR
- ☐ Patient is using in combination with bevacizumab as continuous maintenance therapy, if given first-line as part of bevacizumab/ platinum/and pemetrexed regimen ; OR
- ☐ Patient is using in combination with cemiplimab as continuous maintenance therapy, if given first-line as part of cemiplimab/ platinum/and pemetrexed regimen ; OR
- ☐ Patient is using in combination with durvalumab as continuous maintenance therapy if given first-line as part of tremelimumab/durvalumab/platinum/and pemetrexed regimen ; OR
- ☐ Patient is using as first-line therapy in combination with nivolumab, ipilimumab, and platinum-based chemotherapy and without presence of actionable molecular markers* ; OR
- ☐ Patient is using as adjuvant or neoadjuvant therapy in combination with platinum-based chemotherapy;

OR

☐ Patient is using as a single-agent therapy; AND

☐ Patient has one of the following :

- ☐ Patient has a diagnosis for persistent or recurrent ovarian cancer; OR
- ☐ Patient has a diagnosis for thymic cancer and thymomas and using as second-line therapy and beyond.

If not, please provide **clinical rationale** for formulary exception: _____

_____

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ **Provider has reviewed the attached "Criteria for Continuation" and attests the member meets ALL required PA Continuation criteria.**

☐ Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Oncology: NSCLC Meds PA

Drug Name(s):

PEMETREXED
PEMFEXY
ACCORD
TEVA
ALIMTA
HOPIRA
SANDOZ

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Prescribed by, or in consultation with an oncologist or other cancer specialist related to the diagnosis.
3. Drug is being used appropriately per CMS recognized compendia, authoritative medical literature, evidence-based guidelines and/or accepted standards of medical practice.
4. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

Cannot be prescribed for experimental or investigational use.

Prescriber Restrictions:

Oncologist or other cancer specialist

Coverage Duration:

New Start: Approval will be for 6 months
Continuation: Approval will be for 12 months

FDA Indications:

Pemetrexed Products

- Malignant mesothelioma of pleura, First-line treatment, in combination with cisplatin in patients whose disease is unresectable or who are not otherwise candidates for curative surgery
- Nonsquamous non-small cell lung cancer, Locally advanced or metastatic, first-line treatment in combination with cisplatin
- Nonsquamous non-small cell lung cancer, Locally advanced or metastatic disease, maintenance therapy as a single agent following 4 cycles of platinum-based first-line chemotherapy
- Nonsquamous non-small cell lung cancer, Metastatic disease, first-line treatment in combination with pembrolizumab and platinum chemotherapy, with no EGFR or ALK genomic tumor aberrations
- Nonsquamous non-small cell lung cancer, Recurrent, metastatic disease after prior chemotherapy.

Off-Label Uses:

Pemetrexed Products

- Malignant mesothelioma of pleura
- Nonsquamous non-small cell lung cancer, Stage IIIB/IV or recurrent, continuation maintenance therapy in combination with bevacizumab following platinum-based, first-line therapy
- Ovarian cancer, Recurrent.

Age Restrictions:
Safety and effectiveness not established in pediatric patients

Other Clinical Considerations:
Cancer diagnoses: Criteria as per NCCN or other FDA-approved cancer related guidelines.

Resources:
https://www.micromedexsolutions.com/micromedex2/librarian/CS/BC9046/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/9B6F95/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.DoIntegratedSearch?SearchTerm=Pemetrexed&UserSearchTerm=Pemetrexed&SearchFilter=filterNone&navitem=searchGlobal#