



Chemotherapy: Pemetrexed Drugs (NSCLC) Step Therapy
Pemetrexed: Pemfexy J9304, Pemrydi J9324 are 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.*

<input type="checkbox"/>	Standard Request– (72 Hours)	<input type="checkbox"/>	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

HCP 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	ALIMTA
PEMFEXY	HOPIRA
ACCORD	SANDOZ
TEVA	PEMRYDI

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
- Non-squamous non-small cell lung cancer, Locally advanced or metastatic, first-line treatment in combination with cisplatin
- Non-squamous 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
- Non-squamous 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
- Non-squamous non-small cell lung cancer, Recurrent, metastatic disease after prior chemotherapy.

Off-Label Uses:

Pemetrexed Products

- Malignant mesothelioma of pleura
- Non-squamous 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/DUPLICATIONSHIELDSYN/C/9B6F95/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.DoIntegradSearch?SearchTerm=Pemetrexed&UserSearchTerm=Pemetrexed&SearchFilter=filterNone&navitem=searchGlobal#

CLINICAL / CMS ONLY