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### **Pharmacy Coverage Policy**

Effective Date: April 27, 2022 Revision Date: January 24, 2024 Review Date: January 17, 2024 Line of Business: Medicare, Commercial, Medicaid - South Carolina, Medicaid - Ohio Policy Type: Prior Authorization

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#### **Products Affected**

pemetrexed disodium intravenous powder for solution pemetrexed disodium intravenous solution pemetrexed intravenous powder for solution pemetrexed intravenous solution Alimta intravenous solution Pemfexy intravenous solution

#### **Listed Indications**

Malignant Pleural Mesothelioma Bladder Cancer Cervical Cancer Ovarian Cancer Thymic Malignancy Non-small cell lung cancer (Non-squamous)

Malignant Pleural Mesothelioma		
Does the member meet all of the following criteria?		
Criteria #1	The member must have a diagnosis of malignant pleural mesothelioma	
Criteria #2	• The member must be using pemetrexed as induction therapy in combination with carboplatin or cisplatin for medically operable clinical stage I-III <b>OR</b>	
	The member must be using pemetrexed as a single agent or in combination with cisplatin or carboplatin     OR	
	• The member is using pemetrexed as second-line as a single agent if not administered first-line OR	
	Pemetrexed is being used in combination with bevacizumab product and cisplatin	
Does the member have any of the following exclusions? If yes, approval may not be appropriate.		
NOTE: Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.		
Exclusion #1	Creatinine clearance (CrCl) < 45 ml/minute	
Approval Duration		
Initial	Pemetrexed will be approved in plan year durations or as determined through clinical review.	
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Bladder Cancer		
Does the member meet all of the following criteria?		
Criteria #1	The member must have a diagnosis of metastatic bladder cancer	
Criteria #2	Pemetrexed is being used as second-line or subsequent therapy as a single agent for metastatic disease	
Does the member have any of the following exclusions? If yes, approval may not be appropriate.		
NOTE: Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.		
Exclusion #1	Creatinine clearance (CrCl) < 45 ml/minute	
Approval Duration		

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Cervical Cancer		
Does the member meet all of the following criteria?		
Criteria #1	The member must have a diagnosis of cervical cancer	
Criteria #2	Pemetrexed is being used as a second-line or subsequent therapy as a single agent for	
	local/regional recurrence or distant metastases	
Does the member have any of the following exclusions? If yes, approval may not be appropriate.		
NOTE: Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.		
Exclusion #1	Creatinine clearance (CrCl) < 45 ml/minute	
Approval Duration		
Initial	Pemetrexed will be approved in plan year durations or as determined through clinical review.	
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Ovarian Cancer		
Does the member meet all of the following criteria?		
Criteria #1	The member must have a diagnosis of Ovarian Cancer, or Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer	
Criteria #2	Pemetrexed is being used as a single agent for persistent disease or recurrence therapy.	
Does the member have any of the following exclusions? If yes, approval may not be appropriate. NOTE: Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.		
Exclusion #1	Creatinine clearance (CrCl) < 45 ml/minute	
Approval Duration		
Initial	Pemetrexed will be approved in plan year durations or as determined through clinical review.	
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Thymic Malignancy		
Does the member meet all of the following criteria?		
Criteria #1	The member must have a diagnosis of thymic malignancy	
Criteria #2	Pemetrexed is being used as second-line therapy as a single agent .	
Does the member have any of the following exclusions? If yes, approval may not be appropriate.		
NOTE: Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.		
Exclusion #1	Creatinine clearance (CrCl) < 45 ml/minute	
Approval Duration		
Initial	Pemetrexed will be approved in plan year durations or as determined through clinical review.	
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Non-small cell lung cancer (Non-squamous)		
Does the member meet all of the following criteria?		
Criteria #1	The member must have a diagnosis of nonsquamous locally advanced or metastatic non-small cell lung cancer	
Criteria #2	One of the following applies:	

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	<ul> <li>If EGFR, ALK, ROS1 BRAF negative and PD-L1 less than 1% AND one of the following applies: <ul> <li>Pemetrexed is being used in combination with cisplatin or carboplatin therapy for the initial treatment in members with a performance status (PS) 0-2 OR</li> <li>Pemetrexed is being used in cisplatin or carboplatin-based regimens in combination with bevacizumab product in members with PS 0-1 and no history of hemoptysis OR</li> <li>As a single agent in members with PS 2 OR</li> </ul> </li> <li>If EGFR, ALK, ROS1, BRAF positive and PD-L1 greater than or equal to 1% and after prior therapy AND one of the following applies: <ul> <li>Pemetrexed is being used in cisplatin or carboplatin-based regimens in combination with bevacizumab product in members with cisplatin or carboplatin as subsequent therapy in members with a performance status (PS) 0-2 OR</li> <li>Pemetrexed is being used in cisplatin or carboplatin-based regimens in combination with bevacizumab product in members with PS 0-1 and no history of hemoptysis as subsequent therapy in members with a performance status (PS) 0-2 OR</li> <li>Pemetrexed is being used in cisplatin or carboplatin-based regimens in combination with bevacizumab product in members with PS 0-1 and no history of hemoptysis as subsequent therapy OR</li> <li>As a single agent in members with PS 2 as subsequent therapy OR</li> <li>Pemetrexed is being used as a single agent after prior chemotherapy OR</li> <li>Pemetrexed is being used as a single agent for the maintenance treatment of members whose disease has not progressed after four cycles of platinum-based first-line chemotherapy OR</li> <li>As a single agent for recurrence or metastasis in members who achieved tumor response or stable disease following first-line chemotherapy with Pemetrexed OR</li> <li>Pemetrexed is given in combination with Keytruda (pembrolizumab) and carboplatin or cisplatin as first line therapy for nonsquamous metastatic NSCLC followed by maintenance Keytruda (pembrolizumab)in combination with cisplatin used</li></ul></li></ul>	
	<ul> <li>In combination with cisplatin used as neoadjuvant or adjuvant chemotherapy OR</li> <li>Concurrent chemoradiation in combination with carboplatin or cisplatin</li> </ul>	
Does the member have any of the fo	ollowing exclusions? If yes, approval may not be appropriate.	
NOTE: Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.		
Exclusion #1	Squamous cell non-small cell lung cancer.	
Exclusion #2	Creatinine clearance (CrCl) < 45 ml/minute	
Approval Duration		
Initial	Pemetrexed will be approved in plan year durations or as determined through clinical review.	
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#### Background

This is a prior authorization policy about Pemetrexed.

Refer to the current Full Prescribing Information for specific recommendations about dose adjustments.

Pemetrexed is a pyrimidine-based folate analog that suppresses tumor growth by inhibiting both DNA synthesis and folate metabolism at multiple target enzymes. The multiple enzyme inhibition is unique, as methotrexate inhibits only dihydrofolate reductase, and 5-fluorouracil and raltitrexed inhibit only thymidine synthetase. Thus, Alimta (pemetrexed) may be useful for 5-fluorouracil-, methotrexate-, and raltitrexed-resistant cancers.

Pemetrexed acts as a 'multitargeted' antifolate compound by interrupting both purine synthesis via thymidylate synthase (TS) and dihydrofolate reductase (DHFR) inhibition, and pyrimidine synthesis via glycinamide ribonucleotide formyl transferase (GARFT) and aminoimidazole carboxamide

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formyl transferase (AICARFT) inhibition, which are all key enzymes involved in folate metabolism.

Pemetrexed is FDA approved for unresectable mesothelioma and metastatic/advanced nonsquamous non-small cell lung cancer (NSCLC). Pemetrexed is not indicated for the treatment of squamous cell NSCLC.

Pemetrexed is available as Alimta as 100 mg and 500 mg powder for injection, Pemfexy 500 mg in single-use vials.

#### **Provider Claim Codes**

For medically billed requests, please visit <u>www.humana.com/PAL</u>. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

#### **Medical Terms**

Alimta; pemetrexed; mesothelioma, non-small cell lung cancer; intravenous; Pemfexy; thymic cancer; ovarian cancer; cervical cancer; bladder cancer

#### References

Alimta (pemetrexed [package insert]. Indianapolis, IN. Eli Lilly and Company. January 2019.

Pemfexy(pemetrexed [package insert]. Woodcliff Lake, NJ. Eagle Pharmaceuticals Inc. Februrary 2020.

Clinical Pharmacology [online database]. Tampa, FL: Gold Standard, Inc. URL: http://www.clinicalpharmacology.com. Updated periodically.

Lexi-Comp ONLINE<sup>™</sup> with AHFS<sup>™</sup>, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.

Micromedex<sup>®</sup> Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically.

NCCN Drug and Biologics Compendium. Fort Washington, PA: National Comprehensive Cancer Network (NCCN); Updated periodically.

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