Clinical Criteria

Subject:	**Ethyol (amifostine)**		
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Overview

This document addresses the use of Ethyol (amifostine). Ethyol is an intravenously administered prodrug that is dephosphorylated to a pharmacologically active free thiol metabolite in tissues. This metabolite accumulates to a higher concentration in normal (non-cancer) tissues where it is available to bind to, and thereby detoxify, reactive metabolites of cisplatin and scavenge reactive oxygen species generated by radiation.

Ethyol is FDA approved to reduce the cumulative renal toxicity associated with repeated administration of cisplatin in patients with advanced ovarian cancer. It is also FDA approved to reduce the incidence of moderate to severe xerostomia in patients undergoing post-operative radiation treatment for head and neck cancer, where the radiation port includes a substantial portion of the parotid glands. Ethyol should not be used in other settings where chemotherapy can produce a significant survival benefit or cure, or in patients receiving definitive radiotherapy. The National Comprehensive Cancer Network® (NCCN) does not provide recommendations for the use of Ethyol.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Ethyol (amifostine)

Requests for Ethyol (amifostine) may be approved if the following criteria are met:

I. Individual has a diagnosis of advanced ovarian cancer; AND
II. Individual is using as Prophylaxis in cisplatin nephropathy;

OR

III. Individual has a diagnosis of head and neck cancer; AND
IV. Individual is using for Prophylaxis in post-operative radiation-induced xerostomia.

Requests for Ethyol (amifostine) may not be approved when the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

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HCPCS

J0207	**Injection, amifostine, 500 mg [Ethyol]**

ICD-10 Diagnosis

C56.1-C56.9	**Malignant neoplasm of ovary**
C76.0	**Malignant neoplasm of head, face and neck**
N14.3	**Nephropathy induced by heavy metals**
Z29.9	**Encounter for prophylactic measures, unspecified**
Z85.4	**Personal history of malignant neoplasm of genital organs**

Document History

Revised: 11/15/2019
Document History:

- **11/15/2019 – Annual Review: Wording and formatting changes. Coding Reviewed: Added HCPCS code J0207, Added ICD-10-CM codes C56.1-C56.9, C76.0, N14.3, Z29.9, Z85.4**

References

1. **Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: http://www.clinicalpharmacology.com. Updated periodically.**
2. **DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 8, 2019.**
3. **DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.**
4. **Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.**

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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