**Erwinase® (Erwinia L-asparaginase)**

[For the list of services and procedures that need preauthorization, please refer to www.mcs.pr. Go to "Comunicados a Proveedores", and click "Cartas Circulares".]

**Medical Policy:** MP-RX-03-08  
**Original Effective Date:** November 6, 2008  
**Reviewed:** December 27, 2012  
**Revised:**

This policy applies to products subscribed by the following corporations, MCS Life Insurance Company (Commercial), and MCS Advantage, Inc. (Classicare) and Medical Card System, Inc., provider’s contract; unless specific contract limitations, exclusions or exceptions apply. Please refer to the member’s benefit certification language for benefit availability. Managed care guidelines related to referral authorization, and precertification of inpatient hospitalization, home health, home infusion and hospice services apply subject to the aforementioned exceptions.

**DESCRIPTION**

L-Asparaginase is an enzyme that is used as an antineoplastic agent to treat acute lymphocytic leukemia (ALL). Commonly in clinical use, L-asparaginase is purified from Escherichia coli, although L-asparaginase is available from multiple other sources including Erwinia carotovora (also known as chrysanthemi), Serratia marcescens, and guinea pig serum. The E. carotovora gene for L-asparaginase has been inserted into and is expressed by E. coli. Preparations of L-asparaginase from different bacteria and by different purification methods have slight differences in enzyme characteristics. For example, the E. coli-derived L-asparaginase has a molecular weight of 34,080 daltons, while the E. carotovora enzyme has a weight of 32,000 daltons.

Patients developing an allergic reaction to E. coli preparations have been found to tolerate the Erwinia formulation. As a single agent, L-asparaginase induces remission in 50—60% of ALL patients; however, these remissions are short-lived, only 1—8 months. Therefore, L-asparaginase usually is administered in combination with other drugs (e.g., vincristine and prednisone). L-Asparaginase has no activity in solid tumors; a few responses have been noted in patients with acute myeloid leukemia, chronic myeloid leukemia in blast crisis, or non-Hodgkin's lymphoma treated with L-asparaginase.

**COVERAGE**

Benefits may vary between groups and contracts. Please refer to the appropriate member certificate and subscriber agreement contract for applicable diagnostic imaging, DME, laboratory, machine tests, benefits, and coverage.
INDICATIONS

Medical Card System, Inc (MCS) considers medically necessary the administration of Erwinase® (Erwinia L-asparaginase) under the following indications:

1. For the induction of remission of acute lymphocytic leukemia (ALL) in combination with other chemotherapeutic agents.

2. Members must have either systemic hypersensitivity reactions to native (Elspar®) or pegylated E. Coli asparaginase (Oncaspar®) (including patients with generalized rash with or without anaphylactic symptoms) or patients with previously documented local systemic reactions to E. Coli derived L-asparaginase.

CONTRAINDICATIONS/PRECAUTIONS

1. L-Asparaginase is contraindicated in patients with pancreatitis or a history of pancreatitis due to L-asparaginase therapy.

2. L-asparaginase therapy is contraindicated in patients who have experienced bleeding or thromboembolic disease, including thromboembolic events due to previous L-asparaginase therapy.

3. Patients receiving anticoagulant therapy, aspirin, or NSAIDs may be at increased risk for bleeding problems.

4. Patients with diabetes mellitus may be at increased risk of adverse reactions due to alteration in insulin production or pancreatic insult. Blood sugar should be closely monitored.

5. Hyperkalemia, hyperphosphatemia, hyperuricemia, hypocalcemia, and decreased urine output may be indicative of L-asparaginase-induced tumor lysis syndrome (TLS).

6. Vaccination during chemotherapy or radiation therapy should be avoided because the antibody response is suboptimal.
CODING INFORMATION

ICD-9 CM® Diagnosis Codes (List may not be all inclusive)

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<th>ICD-9 CM® CODES</th>
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<tr>
<td>204.00</td>
<td>Acute Lymphoblastic Leukemia without mention of remission</td>
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<tr>
<td>204.01</td>
<td>Acute Lymphoblastic Leukemia in remission</td>
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*2012 ICD-9-CM® For Physicians, VOLUMES I & II, Professional Edition (American Medical Association)*

HCPCS CODES (List may not be all inclusive)

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<tr>
<td>J9020</td>
<td>Asparaginase 10000 units</td>
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*2012 HCPCS LEVEL II Professional Edition® (American Medical Association)*

REFERENCES


POLICY HISTORY

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<td>November 6, 2008</td>
<td>Origination of Policy</td>
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<td>December 17, 2009</td>
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<td>December 15, 2010</td>
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The following Contraindication/Precaution was deleted from the policy.

- E. coli derived L-asparaginase is contraindicated in patients with E. coli protein hypersensitivity or L-asparaginase hypersensitivity resulting in anaphylactic reactions (e.g., urticaria, acute bronchospasm, laryngeal edema, or hypotension) to E.coli derived L-asparaginase.

- The manufacturer of E. coli L-asparaginase recommends a desensitization procedure for patients at high risk or with previous hypersensitivity to the E. coli product; however, clinically, desensitization is rarely used since alternative products are available (e.g., Erwinia L-asparaginase and pegasparagase).

December 27, 2012
Yearly Review
References updated.