

Erwinaze™ (asparaginase *Erwinia chrysanthemi*)**Sample Claim Denial Appeal Letter for Erwinaze™ (asparaginase *Erwinia chrysanthemi*) For Injection**

[Date]
[Contact]
[Title]
[Name of Health Insurance Company]
[Address]
[City, State, Zip Code]
Insured: [Patient name]
Policy Number: [Policy number]
Group Number: [Group number]
Diagnosis: [Diagnosis and ICD-9-CM code]

Dear [Name of contact]:

This letter serves as a request for reconsideration of a claim representing charges for Erwinaze™ (asparaginase *Erwinia chrysanthemi*) For Injection administered to [patient name] on [date(s) of service]. [Patient name] has been under my treatment for [his/her] diagnosis of [diagnosis]. You have indicated that Erwinaze is not covered by [insurance name] because [reason for denial].

Erwinaze is an asparagine-specific enzyme indicated as a component of a multiagent chemotherapeutic regimen for the treatment of patients with acute lymphoblastic leukemia (ALL) who have developed hypersensitivity to *Escherichia coli*-derived asparaginase.¹ Its use is based on the following:

- Asparaginase is the cornerstone of pediatric ALL therapy² and has shown improved outcomes³⁻⁶
- Maintaining depletion of asparagine is the key to improving outcomes with asparaginase²
- Completing the planned dosing regimen of asparaginase is a crucial part of ALL treatment to improve event-free survival^{7,8}
- Hypersensitivity is a common side effect of asparaginase treatment and is often the reason for discontinuation of asparaginase⁹
- Erwinaze is an alternative to *E coli*-derived asparaginases in patients with hypersensitivity
- There is no cross-reactivity between Erwinaze and *E coli*-derived asparaginases, but there is cross-reactivity between native *E coli* asparaginase and pegylated asparaginase^{10,11}
- Switching to Erwinaze following hypersensitivity to *E coli*-derived asparaginase optimizes treatment outcomes¹²

Because of [insert relevant patient information—history, diagnosis, etc], I have administered Erwinaze as a medically necessary part of this patient's treatment and would appreciate your reconsideration of the [date of service] claim for [patient name]. Please contact me at [physician telephone number, including area code] if you require additional information.

Thank you in advance for your immediate attention to this request.

Sincerely,

[Physician's name]

[Physician's practice or hospital name]

Attachments [references, original claim form, denial/explanation of benefits (EOB), additional supporting documents]

continued

Erwinaze™ (asparaginase *Erwinia chrysanthemi*)**Sample Claim Denial Appeal Letter for Erwinaze™ (asparaginase *Erwinia chrysanthemi*) For Injection****Selected Important Risk Information About Erwinaze¹****Contraindications**

- History of serious hypersensitivity reactions to Erwinaze, including anaphylaxis
- History of serious pancreatitis with prior L-asparaginase therapy
- History of serious thrombosis with prior L-asparaginase therapy
- History of serious hemorrhagic events with prior L-asparaginase therapy

Warnings and Precautions

- If the following occur, discontinue Erwinaze:
 - Serious hypersensitivity reactions, including anaphylaxis
 - Severe or hemorrhagic pancreatitis
- Glucose intolerance can occur and, in some cases, may be irreversible. Perform appropriate monitoring and treat hyperglycemia with insulin, as necessary
- Thrombosis, hemorrhage: discontinue Erwinaze until resolved

Adverse Reactions

- Most common (>1%) adverse reactions are: serious hypersensitivity reactions, including anaphylaxis, pancreatitis, abnormal transaminases, coagulation abnormalities including thrombosis and hemorrhage, nausea and vomiting, and hyperglycemia

Please see full Prescribing Information.

Erwinaze™ (asparaginase *Erwinia chrysanthemi*)**References for Sample Claim Denial Appeal Letter for Erwinaze™
(asparaginase *Erwinia chrysanthemi*) For Injection**

References

1. Erwinaze™ (asparaginase *Erwinia chrysanthemi*) prescribing information. Langhorne, PA: EUSA Pharma (USA), Inc.; November 2011.
2. Pieters R, Hunger SP, Boos J, et al. L-asparaginase treatment in acute lymphoblastic leukemia. *Cancer*. 2011;117:238-249.
3. Ortega JA, Nesbit ME, Donaldson MH, et al. L-asparaginase, vincristine, and prednisolone for induction of first remission in acute lymphocytic leukemia. *Cancer Res*. 1977;37:535-540.
4. Sallan SE, Hitchcock-Bryan S, Gelber R, et al. Influence of intensive asparaginase in the treatment of childhood non-T-cell acute lymphoblastic leukemia. *Cancer Res*. 1983;43:5601-5607.
5. Pession A, Valsecchi MG, Masera G, et al. Long-term results of a randomized trial on extended use of high dose L-asparaginase for standard risk childhood acute lymphoblastic leukemia. *J Clin Oncol*. 2005;23:7161-7167.
6. Amylon MD, Shuster J, Pullen J, et al. Intensive high-dose asparaginase consolidation improves survival for pediatric patients with T cell acute lymphoblastic leukemia and advanced stage lymphoblastic lymphoma: a Pediatric Oncology Group study. *Leukemia*. 1999;13:335-342.
7. Ogawa C, Ohara A, Manabe A, et al. Tokyo Children's Cancer Study Group (TCCSG) Study L99-15 [abstract]. *Blood*. 2005;106. Abstract 878.
8. Silverman L, Gelber RD, Kimball Dalton V, et al. Improved outcome for children with acute lymphoblastic leukemia: results of Dana-Farber Consortium Protocol 91-01. *Blood*. 2001;97:1211-1218.
9. Raetz EA, Salzer WL. Tolerability and efficacy of L-asparaginase therapy in pediatric patients with acute lymphoblastic leukemia. *J Pediatr Oncol*. 2010;32:554-563.
10. Wang B, Relling MV, Storm MC, et al. Evaluation of immunologic crossreaction of anti-asparaginase antibodies in acute lymphoblastic leukemia (ALL) and lymphoma patients. *Leukemia*. 2003;17:1583-1588.
11. Zalewska-Szewczyk B, Gach A, Wyka K, et al. The cross-reactivity of anti-asparaginase antibodies against different L-asparaginase preparations. *Clin Exp Med*. 2009;9:113-116.
12. Vrooman LM, Supko JG, Neuberg DS, et al. Erwinia asparaginase after allergy to *E. coli* asparaginase in children with acute lymphoblastic leukemia. *Pediatr Blood Cancer*. 2010;54:199-205.

www.erwinaze.com**EUSA Pharma**

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Erwinia chrysanthemi