

Specialty Pharmacy Program
Oforta[®] (fludarabine phosphate tablets)

DESCRIPTION

Oforta is an oral tablet formulation of fludarabine, an antimetabolite antineoplastic agent. Oforta is indicated for the treatment of adults with B-cell chronic lymphocytic leukemia.

APPROVAL DURATION

Approval duration: 1 year

APPROVAL CRITERIA

Oforta may be approved based on the following criteria:

- I. Patient is an adult with B-cell chronic lymphocytic leukemia AND
 - A. Patient has not responded to or has experienced disease progression during or after an alkylating agent-containing regimen AND
 - B. Patient is not exhibiting signs and symptoms of neurotoxicity or bone marrow suppression AND
 - C. Patient will not receive concurrent therapy with Nipent (pentostatin) while taking Oforta.

Off-Label Indication(s)

Requests for off-label use of Oforta will be reviewed and approved when sufficiently supported by evidence from major compendia, published peer-reviewed medical literature, nationally accepted practice guidelines, or expert consensus statements. The major compendia that are recognized include AHFS[®] Drug Information, Thomson Micromedex[®], National Comprehensive Cancer Network Drugs and Biologics Compendium[™], and Clinical Pharmacology.