

Ellence (epirubicin)

| Override(s) | Approval Duration |
|---------------------|-------------------|
| Prior Authorization | 1 year |

| Medications |
|----------------------|
| Ellence (epirubicin) |

APPROVAL CRITERIA

Requests for Ellence (epirubicin) may be approved if the following criteria are met:
Individual has a diagnosis of one of the following:

- I. Invasive or inflammatory breast cancer, metastatic, or locally advanced disease (Label, NCCN 1 and 2A); **OR**
- II. Non-Hodgkin Lymphoma - Peripheral T-Cell Lymphoma (NCCN 2A); **OR**
- III. Soft Tissue Sarcoma (NCCN 2A); **OR**
- IV. Uterine Sarcoma (NCCN 2A); **OR**
- V. Merkel Cell Carcinoma (NCCN 2A); **OR**
- VI. Bladder Cancer (NCCN 2A).

Ellence (epirubicin) may not be approved for the following:

- I. Severe myocardial insufficiency; **OR**
- II. Recent myocardial infarction or severe arrhythmias, or previous treatment with maximum cumulative doses of other anthracyclines; **OR**
- III. Severe persistent drug-induced myelosuppression; **OR**
- IV. Severe hepatic impairment (Child-Pugh Class C, or serum bilirubin level greater than 5 mg/dL); **OR**
- V. When the above criteria are not met and for all other indications.

Note:

Ellence (epirubicin) has black box warnings regarding tissue necrosis, cardiac toxicity, secondary acute myelogenous leukemia, dose reduction in individuals with hepatic function impairment, and myelosuppression.

Key References:

1. American Urological Association. Available at: <https://www.auanet.org/about-us/bcg-shortage-info>. Accessed on March 22, 2022.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: March 22, 2022.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on March 22, 2022.
 - a. Bladder Cancer V1.2022. Revised February 11, 2022.
 - b. Breast Cancer V2.2022. Revised December 20, 2021.
 - c. Merkel Cell Carcinoma V2.2022. Revised March 14, 2022.
 - d. Soft Tissue Sarcoma V1.2022. Revised March 29, 2022.
 - e. T-Cell Lymphomas V2.2022. Revised March 7, 2022.
 - f. Uterine Neoplasms V1.2022. Revised November 4, 2021.

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

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.