

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

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 breast cancer, metastatic, or locally advanced disease (label, NCCN 2A); **OR**
- II. Head and Neck Cancers - Cancer of the Nasopharynx (NCCN 2A); **OR**
- III. Non-Hodgkin Lymphoma - Peripheral T-Cell Lymphoma (NCCN 2A); **OR**
- IV. Soft Tissue Sarcoma (NCCN 2A); **OR**
- V. Uterine Sarcoma (NCCN 2A); **OR**
- VI. Merkel Cell Carcinoma (NCCN 2A); **OR**
- VII. 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.

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Key References:

1. American Urological Association. Available at: <https://www.auanet.org/practice-resources/bcg-info/bcg-shortage-notice>. Accessed on April 15, 2020.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. 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: April 15, 2020.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on April 15, 2020.
 - a. Bladder Cancer V3.2020. Revised January 17, 2020.
 - b. Breast Cancer V3.2020. Revised March 6, 2020.
 - c. Head and Neck Cancer V1.2020. Revised February 12, 2020.
 - d. Merkel Cell Carcinoma V1.2020. Revised October 2, 2019.
 - e. Soft Tissue Sarcoma V6.2019. Revised February 10, 2020.
 - f. T-Cell Lymphomas V1.2020. Revised January 6, 2020.
 - g. Uterine Neoplasms V1.2020. Revised March 6, 2020.
 - a. Bladder Cancer V4.2019. Revised July 10, 2019.
 - b. Breast Cancer V2.2019. Revised July 2, 2019.
 - c. Bone Cancer V2. 2019. Revised April 10, 2019.
 - d. Head and Neck Cancer V2.2019. Revised June 28, 2019.
 - e. Merkel Cell Carcinoma V2.2019. Revised January 18, 2019.
 - f. Soft Tissue Sarcoma V2.2019. Revised February 4, 2019.
 - g. T-Cell Lymphomas V2.2019. Revised December 17, 2018.
 - h. Uterine Neoplasms V3.2019. Revised February 11, 2019.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.