



Prior Authorization Approval Criteria

Halaven (eribulin)

Generic name:	Eribulin
Brand name:	Halaven
Medication class:	Antineoplastic: mitotic inhibitor
FDA-approved uses:	Treatment of metastatic breast cancer in patients who have received at least two chemotherapeutic regimens for metastatic disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting
Available dosage forms:	1mg/2ml vial for injection
Usual dose:	1.4 mg/m ²
Approximate cost: (based on AWP 2011)	\$4,200 per 28 days

Criteria for use (*bullet points below are all inclusive unless otherwise noted*):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records
- Clinically diagnosed metastatic breast cancer
- Prior treatment with an anthracycline in either the adjuvant or metastatic setting
- Prior treatment with a taxane in either the adjuvant or metastatic setting
- Prior treatment with at least two chemotherapeutic regimens for the treatment of metastatic disease

Criteria for continuation of therapy:

- Patient responding to treatment without disease progression
- Patient tolerating treatment
- Blood cell counts are being monitored frequently

Caution:

- Dose adjustment are required for hepatic and/or renal impairment
- Dose adjustments are recommended after development of toxicities

Monitoring:

- Complete blood cell count
- Signs of neuropathy

Contraindication:

- None

Not approved if:

- Patient does not meet the above stated criteria
- Neutrophil counts < 1,000/mm³

Special considerations:

- Pregnancy category D: fetal harm is expected
- It is not known if eribulin is excreted into human milk
- Compared to the control arm, median survival was increased by 2.5 months
- Approval will be for one cycle at a time

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 06/08/11