HSCB Service Notification for the managed entry of new medicines and technologies

Health and Social Care Board

1	**Treatment & Condition** Eribulin for treating locally advanced or metastatic breast cancer after 2 or more chemotherapy regimens
2	**Associated appraisal body *&* Summary of ruling** NICE Technology appraisal guidance (TA423), December 2016. Eribulin is recommended as an option for treating locally advanced or metastatic breast cancer in adults, only when: • it has progressed after at least 2 chemotherapy regimens (which may include an anthracycline or a taxane, and capecitabine) • the company provides eribulin with the discount agreed in the patient access scheme. This guidance is not intended to affect the position of patients whose treatment with eribulin was started within the NHS before this guidance was published. Treatment of those patients may continue without change to whatever funding arrangements were in place for them before this guidance was published until they and their NHS clinician consider it appropriate to stop.
3	**Number of people in Northern Ireland expected to take up service/therapy** *(including new cases per year)* Eribulin is an additional treatment option for advanced or metastatic breast cancer that has progressed after 2 or more chemotherapy regimens. Number of people estimated to be eligible for treatment in Northern Ireland (according to NICE Resource Impact Template accompanying TA 423)

Population	***Percentage (%)***	***Number of people***
Adult population of NI		*1,417,588*
Prevalence of breast cancer	*0.14*	*1985*
Prevalence of advanced/ metastatic breast cancer	*7.39*	*147*
People who undergo second line chemotherapy	*65.37*	*96*
People who undergo third line treatment	*52.64*	*50*
*Total number estimated to have Eribulin each year from year 5**	*69.04*	*35*

***** NICE Resource Impact Assessment was informed by the level of prescribing of Eribulin in England in 2014/15 (based on Cancer Drugs Fund returns for 2014/15). Based on this, the expected number in Northern Ireland would therefore be 35 patients.

However, it is the view of local clinicians that the number of patients eligible for treatment in Northern Ireland would be in the region of 50 per annum.

The NICE resource impact template makes the following assumptions:

- No vial sharing, all vials used are rounded up
- Pack sharing for oral drugs is assumed to happen.
- In all regimens, treatment will continue until disease progression.
- The level of eribulin prescribing will not change when it is available through routine commissioning.
- When eribulin is not prescribed, half of people will be prescribed vinorelbine, a quarter will be prescribed gemcitabine and the remainder will be prescribed either doxorubicin, paclitaxel or docetaxel

4. **Patient Access Scheme Availability**

(**Yes**/No)

The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of eribulin, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence. The Department of Health considered that this patient access scheme does not constitute an excessive administrative burden on the NHS.

5. **Costs** *(before PAS if applicable)*

The recommended dosage of eribulin as the ready to use solution is 1.23 mg/m^2 administered intravenously over 2 to 5 minutes on days 1 and 8 of every 21-day cycle.

The cost of eribulin is £361.00 per 0.88 mg/2 ml solution for injection vial and £541.50 per 1.32 mg/3 ml solution for injection vial (as per NICE Resource Impact Template; excluding VAT; British national formulary [BNF] online, accessed by NICE September 2016).

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5.1 **Drug cost per patient per annum (for new and prevalent cases)**

Eribulin (1.32 mg)	
Packs or vials per cycle	*4*
Cost per pack or vial	*£541.50*
Administration costs	*£301.00*
Cost per cycle	*£2,467.00*
Average progression free survival (months)	*4.56*
Cycle length (days)	*21*
Average number of cycles per month	*1.43*
*Number of cycles per year**	*6.51*
Annual cost	*£16,070.74*

	When calculating dosage, an average weight of 76kg and an average skin surface area of 1.8m2 has been assumed (as per the NICE Resource Impact Template accompanying TA 423). Administration costs are based on HRG SB11Z for oral treatments and SB13Z for IV administration *Calculation:* Dose = 1.23mg/m2 on day 1 and 8 of every 21 day cycle. If body surface area of 1.8m2, 2.214mg required on each administration (1.23 x 1.8) Two vials of 1.32mg/3ml are required for the correct dose (2.64mg in total in these two vials). Two administrations per cycle, therefore 4 vials are required per cycle. Cost per vial = £541.50 (note this is **before Patient Access Scheme is applied**) 1.43 cycles per month. 4.56 x 1.43 = 6.51.* Annual cost =£6.51 x 2,467 = £16,070.74. *Number of cycles per year is based on the number of cycles within 4.56 months, as there is an average progression free survival of 4.56 months. The NICE Impact Template assumes that treatment will continue until disease progression.
5.2	**Total Drug Costs Per annum** 50 patients are expected to be eligible for treatment per year. £16,070.74 x 50 = £803,537
5.3	**Infrastructure costs Per annum** Any additional infrastructure costs associated with the introduction of new cancer therapies will be dealt with as part of the routine commissioning process.
6.	**Expected implementation period** No implementation period is anticipated.
7.	**Commissioning arrangements** This regimen will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost-per-case (CPC) basis for a period of 12 months. After this time, numbers of patients who received or are receiving treatment will be reviewed and consideration will be given to moving to recurrent funding to support this regime.
8.	**Monitoring arrangements** The HSCB cost per case process will generate quarterly reports on the number of applications. HSCB currently routinely reviews quarterly monitoring information in relation to the usage of all recurrently funded specialist cancer drugs across both the Cancer Centre and other Units. The monitoring pro forma will be adapted to capture information in respect of this regimen and this group of patients. This monitoring report is submitted to the Specialist Services Commissioning Team for formal review and comment by the Team.

9.	**DoH (NI) Legislative/Policy Caveats** This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.