

28th August 2009

Jeremy Powell
Technology Appraisal Project Manager
National Institute for Health and Clinical Excellence
MidCity Place
71 High Holborn
London
WC1V 6NA

Dear Mr Powell.

Azacitidine for the treatment of myelodysplastic syndromes (MDS), chronic myelomonocytic leukaemia (CMML) and acute myeloid leukaemia (AML) – Patient Access Scheme

Celgene have proposed a patient access scheme (PAS) as part of the current single technology appraisal of azacitidine for the treatment of MDS, CMML and AML. This proposed PAS has been submitted for review by the Department of Health and has been sent to the Appraisal Committee as part of Celgene's response to the Appraisal Consultation Document (ACD).

Celgene would like to provide to the Appraisal Committee an overview of the proposed PAS as part of their reconsideration of the ACD.

Patient Access Scheme - an overview:

- The proposed PAS is a 7% discount on the NHS list price of azacitidine which is currently £321 per 100mg/4mL vial of powder for suspension for injection.
- The discount will be temporary, applicable until such time that Celgene makes an additional vial strength commercially available in the United Kingdom.

Discount based-scheme – rationale:

- As noted in the 2009 Pharmaceutical Price Regulation Scheme regarding financially-based PAS, Celgene have proposed a discount that avoids any administrative or logistical burden to the NHS.
- The 7% discount in the proposed PAS is based on the current list price of azacitidine across the major European markets. At current and historical (preceding 6 month) pound sterling and Euro foreign exchange rates, a 7% discount would put the UK price in-line, if not slightly below, the current lowest price of azacitidine in Europe.
- The proposed discount supports the current European pricing equity of azacitidine. A larger discount could erode this pricing equity.

We hope that this additional information provides an understanding of the rationale behind the proposed PAS and demonstrates our commitment to facilitate patient access for the treatment of a rare, life-threatening blood cancer, whilst helping fulfil the Institute's mandate of securing value-for-money for the NHS.

Yours sincerely,

Tuomo Patsi Regional Vice President, Northern Europe