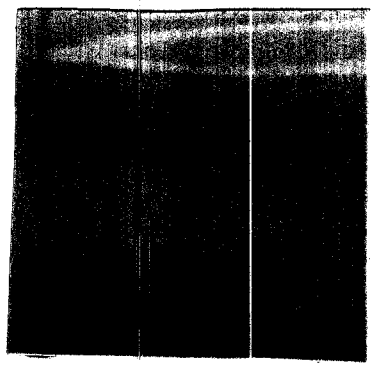
NHS

North of England
Cancer Network



19th August 2009

Jeremy Powell
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Dear Jeremy,

Comments on behalf of Stockton PCT on the Single Technology Apriasal of Azacytadine for the treatment of Myelodyspastic syndromes, Chronic Myelomonocytic Leukaemia and Acute Myeloid Leukaemia.

I have been asked, by Stockton PCT, in my role as Network Pharmacist for the North of England Cancer Network to prepare a response to the above technology appraisal on their behalf. My comments on the Appraisal Consultation Document and the Evaluation Report are given below.

There are a few technical details I wished to highlight, In addition there are one or two issues that may have been discussed at the appraisal committee but which I am are not clear if any concerns have been addressed as they are not mentioned in the ACD.

2.3 I note that the estimated cost of Azacytadine is quoted as 9 vials per cycle - this is incorrect. A typical patient will require two vials per dose and will receive 7 doses. The drug has a short shelf life once mixed and it will not be possible to share vials across multiple days. This will affect any planning documents if this treatment is to be approved. It is unclear if this lower cost has been used in the economic evaluation as there is no actual explanation of the cost of Azacytadine provided in the evaluation report.

3.8 I note that the manufacturer estimated resource use *"based on expert opinion"* -the validity of this does not appear to have been questioned and I would have expected the ERG to have sought further information regarding this. From our local intelligence there would appear to be significant inter-clinician variation in the management of MDS and particularly in the prescribing of supportive treatments.

Drug Costs were derived at BNF Prices, for many supportive medications the drug costs will be significantly discounted which is not reflected in these costs. On the other hand I do not believe any discount will be available for Azacytadine as there is no direct competitor product. This would result in a higher relative drug cost overall from that considered in the economic case.

"..the manufacturer stated that additional infrastructure may be required." I am certain that additional infrastructure will definitely be required. This is of significance because most chemotherapy services operate on a 5 day a week service. In addition to nursing infra-structure, because of the short shelf life of the mixed product there would be a need to provide a 7 day a week pharmacy cytotoxic reconstitution service. Both nursing and pharmacy services nationally struggle with capacity on a 5 day a week service, and the need to expand this to a 7 day a week service would deplete existing resources. The relatively small patient numbers being treated on a Saturday and Sunday, combined with higher overhead costs would make administration costs to the NHS higher than the standard costs experienced during the normal working week.

Pharmacy and Nursing staff operating at weekends would need significant chemotherapy experience to be able to work with a degree of clinical independence without the backup of on-site medical staff experienced in chemotherapy.

5.1 In view of my comments above, regarding the need to develop infrastructure, this technology presents significant barriers to implementation. If NICE were to change its current recommendation, this would require time to recruit and train specialist staff to provide an expanded service without compromising the safety of the already fragile Monday to Friday services. I do not think this can be achieved within the 90 day time limit.

6.1 As highlighted above, there remains significant variations within the practice with regard to treatment of MDS. There may be a need to undertake further research to estimate the current economic costs of treating MDS nationally. This could then support future economic assessments.

I hope the committee find these comments useful, should anything be unclear please do not hesitate to contact me.

Yours sincerely