NHS ENGLAND SPECIALISED SERVICES CLINICAL PANEL REPORT

Date:	17 April 2019. Agenda item 6.3
Intervention:	Dexrazoxane for the prevention of anthracycline (or related drug) induced cardiotoxicity
Indication:	Children and young people (under 25 years) receiving anthracyclines (or related drugs) for cancer
ID:	1825
Gateway:	Policy Gateway 2
Programme:	Cancer
CRG:	Children and Young People's Cancer

Information provided to the panel

Policy proposition

Evidence review produced by NICE Medicines and Technologies Programme on behalf of NHS England Specialised Commissioning in January 2019

CPAG Summary Report

Key elements discussed

A drug that was originally contraindicated in children but the licence has now changed so it can be used for doses beyond 300mg per m^2 during the course of their treatment. A drug that is given alongside anthracyclines. Anthracyclines are used in a number of childhood cancers.

Clinicians tend to avoid high doses of anthracyclines. Over a long period of time there is a risk of cardiotoxicity. Initially dexrazoxane was avoided in children because of the risk of developing a second cancer.

Three papers. One Randomised Controlled Trial (RCT) was an abstract. 5 RCTs in various haematological cancers. Range of ages from 1-21 years old. Long term study from 3 papers of drug toxicity was equally in a young age group. A good spread of studies, mostly RCTs. We can be confident the drug is effective and safe.

Overall Survival - no difference in the safety study (did the drug cause secondary cancer). Clinical cardiotoxicity - no benefit in randomised trial but non-randomised showed benefit, markers of cardiac toxicity show benefit. Surrogate markers give early indication of cardiac complication.

The real benefit on cardiac outcome is not known.

No significant different in side effects.

There is an upper limit to the dose of dexrazoxane.

Population described is similar to evidence.

Intervention the same.

Comparators with no treatment.

Within the evidence review there is a description of the potential harms because there was a concern that increased use was associated may lead to second malignancy. Panel noted that the comparators in the evidence review were plausible.

Recommendation

The policy should proceed to stakeholder testing.

Why the panel made these recommendations

Panel noted that the clinical benefit of a definite improvement in clinical cardiac toxicity has not been demonstrated by the evidence review. However, when using markers of cardiac injury, there is suggestion that using the drug would allow higher doses of chemotherapy to be used for this paediatric population. The understanding of the linkage between surrogate markers and ultimate cardiac toxicity would need to be understood to fully understand the potential benefits of treatment. The policy proposition was therefore suitable to progress to stakeholder testing as routine commissioning.

Documentation amendments required

Panel requested that the policy is amended to clarify the limit on the dose of dexrazoxane used as per the SPC.

Declarations of Interest of Panel Members: None

Panel Chair: James Palmer, Medical Director