

**CPAG Summary Report for Clinical Panel – 1602 Clofarabine for relapsed or refractory acute myeloid leukaemia (AML) as a bridge to stem cell transplant**

<b>The Benefits of the Proposition</b>			
<i>No</i>	<i>Outcome measures</i>	<i>Grade of evidence</i>	<i>Summary from evidence review</i>
1.	Survival	There is no survival benefit [B]	<p>Overall survival (OS) is the length of time from either diagnosis or start of treatment that the patient is still alive.</p> <p>The CLASSIC I trial measured median survival in months. The combination of clofarabine plus cytarabine (chemotherapy drugs) led to a median survival of 6.6, compared to placebo plus cytarabine which led to 6.3 months.</p> <p>These differences were not found to be statistically significant</p>
2.	Progression free survival	There is a survival benefit [B]	<p>Progression-free survival (PFS) is the length of time from either diagnosis or start of treatment to disease progression or patient death from any cause.</p> <p>The CLASSIC I trial examined median disease free survival and found that this was 8.1 months clofarabine plus cytarabine, versus 7.0 with placebo plus cytarabine.</p>

			No statistical tests were reported on the significance of these findings.
3.	Mobility	Not measured	
4.	Self-care	Not measured	
5.	Usual activities	Not measured	
6.	Pain	Not measured	
7.	Anxiety / Depression	Not measured	
8.	Replacement of more toxic treatment	Not measured	
9.	Dependency on care giver / supporting independence	Not measured	
10.	Safety	Adverse events identified [B]	Serious adverse events (side effects) occurred in 60% of patients given clofarabine and cytarabine, and 49% given cytarabine alone. Serious infections occurred in 38% of patients given clofarabine and cytarabine compared with 22% of patients given cytarabine alone. Most common grade 3 to 4 adverse events in the clofarabine group were fever, tiredness, low blood platelet count, pneumonia, iron deficiency, low white blood cell count and increased liver enzymes.
11.	Delivery of intervention	Not measured	

**Other health outcome measures determined by the evidence review**

<i>No</i>	<i>Outcome measure</i>	<i>Grade of evidence</i>	<i>Summary from evidence review</i>
1.	Complete remission	Grade B	<p>Complete remission is where there is no detectable disease following a course of treatment.</p> <p>The proportion of patients in whom complete remission was achieved with clofarabine plus cytarabine was 35.2%. The proportion achieved with placebo plus cytarabine was 17.8% (<math>p &lt; 0.01</math>).</p>

Draft for consultation