Axicabtagene ciloleucel for treating diffuse large B-cell lymphoma and primary mediastinal large B-cell lymphoma after 2 or more systemic therapies (CDF Review of TA559)

For public – AIC, CIC and cPAS redacted

Technology appraisal committee C [06 December 2022]

Chair: Richard Nicholas

Lead team: Natalie Hallas, Alex Cale, Ugochi Nwulu

Evidence assessment group: Kleijnen Systematic Reviews

Technical team: Lewis Ralph, Vicky Kelly, Ross Dent

Company: Kite, a Gilead Company

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Recap: Summary of original appraisal (TA559) and CDF Review

1st and 2nd committee meetings (July and Sept 2018) Guidance published and CDF entry (Nov 2018)

CDF Data collection ends (Feb 2022) CDF Review (ID3980) ACM1 (Sept 2022) CDF Review (ID3980) ACM2 (Nov 2022)

CDF Review (ID3980) ACM3 (Dec 2022)

ID3980 Decision: The committee were satisfied with the company model. Company and ERG base case analyses were consistent and was appropriate for decision making. Committee would have preferred to have seen longer-term PFS data but acknowledged constraints within the trial design. Would have also preferred more sensitivity analyses around utility values in "cured" patients.

Remaining decision-impacting uncertainty limited to the cost of delivering CAR-T therapy on the NHS

- Company used a bottom-up costing approach using sources commonly used in technology appraisals but argued to not capture increased staff time required for CAR-T
- NHSE tariff more costly than the company approach Implications for cost effectiveness

To address uncertainties, further data was provided by NHSE. Tariff reduced from £96k to £61k at ACM2. Concerns of double counting in scenarios run with £61k tariff.



ACM1 base case results – includes original axi-cel PAS ERG and company base case aligns, not including tariff

Deterministic incremental base case results - presented at ACM1

Technology	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£/QALY)
BSC					
Axi-cel					

Results with <u>original</u> axi-cel PAS,

Deterministic incremental base case results – post-ACM1*

Technology	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£/QALY)
BSC					
Axi-cel					

Results with <u>original</u> axi-cel PAS,

^{*}The NICE technical team identified an error in the company's model regarding length of stay during administration and the company provided an updated model



Updated company analysis

- At ACM2, the committee considered a cost of £60,000 appropriate for delivering CAR-T therapy.
- However, concerns still remained about the potential for double counting in the analysis
 - Namely, costs included in the NHSE tariff that were separately accounted for by the company's bottom-up costing approach
- The company proposed a new analysis, using a £41,101 (in line with the EAG analysis seen in ID1684)
 - Removing all other costs relevant to the delivery of CAR-T for the first 100 days following infusion
- NHSE have accepted this as a total cost for the first 100 days and recommend NICE consider this in all ongoing CAR-T appraisals
- Since ACM2, the company has increased the axi-cel PAS to \\times_\%, accepted by NHSE

Cost category	Model value set to £0 for analysis
Axi-cel leukapheresis costs	
Hospitalisation costs for conditional chemotherapy	
Weighted average cost of CRS	
Hospitalisation costs for axi-cel administration	
Axi-cel costs for weighted average cost of allogenic SCT	
Training costs	
Medical resource use costs for the first 3 months (~100 days)	
Hypogammaglobulinemia costs for the first 3 months (~100 days)	
Total costs removed for £41,101 analysis by Gilead	



Updated results – includes updated axi-cel PAS *ERG and company base case aligns, including tariff*

Deterministic incremental base case results – post-ACM1 including tariff

Technology	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£/QALY)
BSC					
Axi-cel					

Results with <u>updated</u> axi-cel PAS,



Updated results – includes updated axi-cel PAS *ERG and company base case aligns, including tariff*

Deterministic incremental base case results – post-ACM1 including tariff

Technology	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£/QALY)
BSC					
Axi-cel					

Results with <u>updated</u> axi-cel PAS,



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Thank you.

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