Technology Guidance

Equecabtagene autoleucel

for relapsed or refractory multiple myeloma

Technology Guidance from the MOH Drug Advisory Committee

Guidance Recommendations

The Ministry of Health's Drug Advisory Committee has recommended:

- ✓ Equecabtagene autoleucel suspension for intravenous infusion for treating patients 18 years of age and above with relapsed or refractory multiple myeloma who have received at least three prior lines of treatment (including a proteasome inhibitor and an immunomodulatory agent), and have demonstrated disease progression on the last therapy.

Funding status

Equecabtagene autoleucel suspension for intravenous infusion is recommended for inclusion on the MOH Cell, Tissue and Gene Therapy Product (CTGTP) List for the abovementioned indication from 1 December 2026.

Equecabtagene autoleucel should be used in line with the additional clinical criteria listed in the Annex.

Published: 5 October 2026

Technology Evaluation

1.1. At the July 2026 meeting, the MOH Drug Advisory Committee ("the Committee") considered the technology evaluation of equecabtagene autoleucel ("equecabtagene") for relapsed or refractory multiple myeloma (r/r MM) in patients who have received at least three prior lines of treatment (including a proteasome inhibitor [PI] and an immunomodulatory agent [IMiD]), and have demonstrated disease progression on the last therapy. The evaluation considered the company's evidence submission by IASO Bio for equecabtagene (Fucaso), and a review conducted by one of ACE's evidence review centres.

1.2. Expert opinion from clinicians at public healthcare institutions, the MOH Cancer Drug Subcommittee, and patient experts from local patient and voluntary organisations helped ACE ascertain the clinical value of equecabtagene.

1.3. The evidence was used to inform the Committee's deliberations around four core decision-making criteria:

- Clinical need of patients and nature of the condition;
- Clinical effectiveness and safety of the technology;
- Cost effectiveness (value for money) – the incremental benefit and cost of the technology compared to existing alternatives; and
- Estimated annual technology cost and the number of patients likely to benefit from the technology.

1.4. Additional factors, including social and value judgments, may also inform the Committee's funding considerations.

Clinical need

2.1. In Singapore, approximately 120 new patients are diagnosed with multiple myeloma each year. It is estimated that 11 of these patients would be eligible for treatment with equecabtagene, a chimeric antigen receptor T-cell (CAR-T) therapy targeting the B-cell maturation antigen (BCMA), after at least three prior lines of treatment (i.e. fourth-line setting and beyond [4L+]).

2.2. In 4L+ r/r MM, there is no established treatment pathway, and patients commonly cycle through combination regimens comprising drug classes used in earlier lines of treatment. Equecabtagene is expected to replace combination regimens incorporating a PI, an IMiD and/or an anti-cluster of differentiation 38 antibody in the 4L+ setting.

2.3. The submission nominated standard of care (SoC) as the comparator for the evaluation, represented by a basket of combination regimens. While the inclusion of isatuximab with pomalidomide and dexamethasone, carfilzomib with cyclophosphamide and dexamethasone, and carfilzomib with dexamethasone as comparators was considered appropriate, comparisons with daratumumab-based regimens, which are primarily used in earlier lines, and alternative BCMA-targeted therapies, which are currently not funded, were considered of limited relevance. In addition, the exclusion of other pomalidomide-based regimens from the comparator basket was considered inappropriate.

2.4. The Committee considered 34 testimonials from local patients and carers describing the significant physical and psychological impacts of multiple myeloma. Patients reported bone pain, weakened immunity, and fear of fractures and relapse, which affected their work, social and physical activities. While patients with r/r MM generally considered their treatments effective with manageable side effects, the financial burden of treatment and follow-up care was their greatest concern. Most patients were willing to accept additional side effects of a new treatment if it could prevent disease progression but were less willing to pay more without survival benefits. Overall, patients valued treatments that could slow or prevent disease progression, improve quality of life, extend survival, were affordable, and had manageable side effects.

Clinical effectiveness and safety

3.1. The Committee reviewed the clinical evidence for equecabtagene from the ongoing Phase I/II, open-label, single-arm trial (FUMANBA-1) in patients with 4L+ r/r MM. The trial reported an overall response rate of 91% and a median overall survival (OS) of 54 months among patients treated with equecabtagene.

3.2. In the absence of direct comparative clinical evidence, the submission presented an unanchored matching-adjusted indirect comparison (MAIC) between equecabtagene and SoC, with SoC proxied by the treatment mix received by patients with late-line r/r MM enrolled in a prospective observational study (LocoMMotion). While the results of the MAIC favoured equecabtagene for progression-free survival (PFS) and OS (Table 1), the Committee considered the findings to be uncertain. This was due to the inadequate adjustment for known prognostic variables and the inherent limitations of unanchored comparisons, which cannot control for unmeasured or unknown confounders. Furthermore, the heterogeneous mix of treatment regimens received by patients in the LocoMMotion study may have limited its generalisability to the local setting.

Table 1: MAIC results for equecabtagene and SoC

Outcome	Progression-free survival	Overall survival
HR (95% CI)	0.203 (0.148, 0.279), p<0.001	0.260 (0.180, 0.375), p<0.001

Abbreviations: CI, confidence interval; HR, hazard ratio; MAIC, matching-adjusted indirect comparison; SoC standard of care.

3.3. In terms of safety, the submission did not present a therapeutic safety claim or a comparative analysis of safety outcomes between equecabtagene and SoC. Interpretation of safety outcomes was limited to the FUMANBA-1 trial which reported high rates of serious treatment-emergent adverse events. The Committee also noted the inherent risk of severe inflammatory adverse events associated with CAR-T therapies like equecabtagene.

3.4. The submission described equecabtagene as superior in effectiveness to SoC in patients with r/r MM who have received at least three prior lines of treatment. Based on the available evidence, the Committee considered equecabtagene to be superior in effectiveness to SoC, but the magnitude of clinical benefit remained uncertain. The Committee considered equecabtagene to have an inferior safety profile compared with SoC.

Cost effectiveness

4.1. The Committee considered the results of the submission's cost-utility analysis that compared equecabtagene with SoC in patients with r/r MM who have received at least three prior lines of treatment, based on the unanchored MAIC. Key components of the base-case economic evaluation provided in the submission are summarised in Table 2.

Table 2: Key components of the company-submitted base-case economic evaluation

Component	Description
Type of analysis	Cost-utility analysis
Population	Adult patients with r/r MM after at least three prior lines of treatment (including a PI and an IMiD) and have demonstrated disease progression on the last therapy.
Outcomes	Total and incremental direct medical costs; total and incremental LY; total and incremental QALYs; ICER
Perspective	Singapore healthcare system
Type of model	Partitioned survival model
Time horizon	15 years (lifetime horizon in the base case) based on a median follow-up of 39.7 months in FUMANBA-1
Health states	Pre-progression; post-progression; death
Cycle length	1 week
Extrapolation methods used to generate results	Equecabtagene Weighted individual patient data derived from the unanchored MAIC between FUMANBA-1 and LocoMMotion were extrapolated using the following parametric models: • OS: exponential • PFS: exponential SoC Digitised OS and PFS KM curves from LocoMMotion were extrapolated using the following parametric models. • OS: log-logistic • PFS: generalised gamma For the base case, a linear waning assumption was applied from year 5 onwards, whereby the treatment effect declined linearly towards near 'equivalence' with SoC at year 15.
Health-related quality of life	Health state utilities were derived from Wu et al. (2023) who collected EQ-5D data from the open-label trial of r/r MM patients treated with ciltacabtagene autoleucel or idecabtagene vicleucel. Of note, the submission claimed that equecabtagene had a different safety profile compared with other CAR-T therapies. On this basis, the post-12-month progression-free utility value was applied directly in the base case, without incorporating the lower utility values observed during the first-year post-infusion. • Progression-free: 0.87 • Progressed disease: 0.72
Types of healthcare resources included	• Drug and drug administration • Disease management cost • Subsequent treatment costs • AE management costs

Abbreviations: AE, adverse event; CAR-T, chimeric antigen receptor T-cell; ICER, incremental cost-effectiveness ratio; IMiD, immunomodulatory agent; KM, Kaplan-Meier; LY, life year; OS, overall survival; PFS, progression-free survival; PI, proteasome inhibitor; QALY, quality-adjusted life year; r/r MM, relapsed or refractory multiple myeloma; SoC, standard of care.

4.2. The base-case incremental cost-effectiveness ratio (ICER) in the submission was between SG$75,000 and SG$105,000 per quality-adjusted life year (QALY) gained. However, the Committee considered the ICER to be uncertain and likely underestimated, in view of the following:

- The submitted model was primarily limited by the uncertain magnitude of clinical benefit of equecabtagene versus SoC, which was informed by the unanchored MAIC.
- The submission applied a time horizon of 15 years in the base case. The Committee considered the time horizon to be optimistic, given the poor prognosis of r/r MM patients and shorter median follow-up duration of 39.7 months in the FUMANBA-1 trial.
- The health state utilities used in the model were uncertain given the absence of patient-reported outcomes in the FUMANBA-1 trial.
- The submission inappropriately applied treatment effect waning for equecabtagene, resulting in a counterintuitive decrease in the ICER result.
- The submission applied different treatment costs for equecabtagene and the comparators arising from alternative data sources and assumptions, and omitted key cost components including bridging therapy, which favoured equecabtagene.

4.3. The Committee considered the respecified base case, which addressed several uncertainties in the company's model, including the time horizon, health state utilities, treatment effect waning and cost inputs. These changes increased the ICER to between SG$105,000 and SG$135,000 per QALY gained. On balance, taking into account the overall proposal, the Committee considered equecabtagene likely to represent an acceptable use of healthcare resources in the local setting for treating 4L+ r/r MM.

Estimated annual technology cost

5.1. Using an epidemiological approach, the submission estimated that the annual cost impact to the public healthcare system would increase from less than SG$1 million in the first year, to between SG$5 million and SG$10 million in the fifth year of listing equecabtagene on the MOH CTGTP List for treating 4L+ r/r MM.

5.2. The Committee considered that the submission's financial estimates were high due to the inclusion of a broader patient population as compared to the submitted evidence, double counting of patients in the calculation, and overestimation of resident growth rates. Based on the respecified budget impact model, the annual cost impact to the public healthcare system was estimated to be less than SG$1 million in the first year, and between SG$1 million and SG$3 million in the fifth year of listing. The Committee also noted the small projected number of eligible patients and considered that the proposed price-volume agreement caps were reasonable relative to the estimated annual cost impact and adequate to manage budget uncertainty.

Recommendations

6.1. The Committee recommended equecabtagene autoleucel suspension for intravenous infusion be included on the MOH CTGTP List for treating patients 18 years of age and above with r/r MM who have received at least three prior lines of treatment (including a PI and an IMiD), and have demonstrated disease progression on the last therapy. The decision was based on the acceptable clinical effectiveness and pricing proposal by the company.

6.2. The Committee also recommended that equecabtagene be used in line with additional clinical criteria (listed in the Annex) to govern appropriate use in local practice.

ANNEX

Clinical criteria for equecabtagene autoleucel for relapsed or refractory multiple myeloma after at least three prior lines of treatment

Treatment of patients 18 years of age and above with relapsed or refractory multiple myeloma (r/r MM) who have received at least three prior lines of treatment (including a proteasome inhibitor and an immunomodulatory agent), and have demonstrated disease progression on the last therapy, who also satisfy the requirements below:

- the patient must have an Eastern Cooperative Oncology Group ("ECOG") performance status of 0 or 1;
- the patient must not have any of the following:
  (i) active graft-versus-host disease;
  (ii) any active central nervous system (CNS) involvement; or
  (iii) any uncontrolled infection, including but not limited to HIV, active hepatitis B or active hepatitis C;
- the patient must have sufficient organ function (e.g. renal, cardiac, and pulmonary function); and
- the patient must not have received any prior B-cell maturation antigen (BCMA)-targeted chimeric antigen receptor T-cell (CAR-T) therapy for r/r MM.

Agency for Care Effectiveness - ACE Agency for Care Effectiveness (ACE)

About the Agency

The Agency for Care Effectiveness (ACE) was established by the Ministry of Health (Singapore) to drive better decision-making in healthcare through health technology assessment (HTA), clinical guidelines, and education.

As the national HTA agency, ACE conducts evaluations to inform government funding decisions for treatments, diagnostic tests and vaccines, and produces guidance for public hospitals and institutions in Singapore.

The guidance is not, and should not be regarded as, a substitute for professional or medical advice. Please seek the advice of a qualified healthcare professional about any medical condition. The responsibility for making decisions appropriate to the circumstances of the individual patient remains with the healthcare professional.

Find out more about ACE at https://www.ace-hta.gov.sg/about-us/

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