

26 November 2020

Cost Recovery Charging Procedure for Independent Review of Company Evidence Submissions to the Agency for Care Effectiveness

INTRODUCTION

The Agency for Care Effectiveness (ACE), Ministry of Health (MOH) Singapore will begin accepting evidence submissions from pharmaceutical companies for oncology drugs in 2021. This new process will enable participating companies to submit evidence to ACE for evaluation close to the anticipated date of regulatory approval by the Health Sciences Authority (HSA) and expedite funding consideration of their oncology products compared to existing evaluation timelines¹. The procedures and guidelines that companies are expected to follow when preparing an evidence submission are available on the ACE website at <https://go.gov.sg/company-guidelines>.

2. All submissions received by ACE will be reviewed and critiqued by one of ACE's Independent Evidence Review Centres (IERCs), which have experience in conducting and appraising health technology assessments (HTAs) for drug funding decision-making. As part of the new submission process, effective from 1 January 2021, companies will be responsible for paying the cost of the independent critique on a cost recovery basis.

3. This document provides information about the type of charges for an IERC critique, and guidance on payment methods and refunds.

CHARGING PROCEDURE FOR COST RECOVERY

4. All companies that intend to provide an evidence submission to ACE will submit a pre-submission form, and discuss and confirm the type of submission (i.e. full or expedited evaluation) and the anticipated submission timelines with ACE during a pre-submission meeting. More information about the pre-submission process is detailed in the guidelines.

5. After the pre-submission meeting, ACE will issue a Letter of Offer to the company seeking their agreement to have their evidence submission reviewed and critiqued by an IERC at the stated charge based on the indicated submission type. Once the Letter of Offer has been accepted and signed by the company and returned to ACE, it will form a contractual agreement between the company and ACE.

6. Upon receipt of a signed Letter of Offer from a company, ACE will issue an invoice, containing a unique identifying number (i.e. invoice number) via email at least 8 weeks before the evidence submission is due. All charges must be paid in full within 30 calendar days from the date of the invoice before ACE will accept the company's evidence submission and send it to an IERC for critique. Payment in installments or by milestones is not permitted.

7. ACE will accept payment in Singapore dollars via Electronic Bank Transfer (e.g. telegraphic transfer) or any other payment method as per the instructions provided in the

¹ Methods and processes for topics which are evaluated in-house by ACE technical staff and are not subject to the new company-led submission process are on the ACE website at www.ace-hta.gov.sg.

invoice. The invoice number must be entered in the free-text portion of the transaction when payment is made.

8. ACE is not responsible for any fees charged during the transfer process. If withholding taxes are imposed by the tax authorities on any payments to ACE, the company is responsible for making payment directly to the relevant authorities on a timely basis. Any other additional costs and taxes incurred by ACE for receiving an overseas payment, such as bank processing fees for telegraphic transfers or foreign currency, should also be borne by the company. When making the telegraphic transfers, the charge code should be indicated as “OUR” in the payment instruction.

9. Please refer to **Annex A** for a diagram of the charging procedure.

CHARGING SCHEDULE (2021/2022)

10. Table 1 outlines the charges in 2021/2022 for an IERC to review and critique a submission for full or expedited evaluation. All charges stated in Table 1 are inclusive of Singapore’s Goods and Services Tax (GST) at a prevailing rate of 7%, which is payable by the company.

Table 1: Charges for Review & Critique of Evidence Submission by IERC

Type of Critique	2021/2022 Charges
Review and Critique of Submission for Full Evaluation	SGD90,950 including GST (SGD85,000 excluding GST)
Review and Critique of Submission for Expedited Evaluation	SGD38,520 including GST (SGD36,000 excluding GST)

11. The charges take into account the time and personnel required by the IERC to complete a written critique of the evidence submission and to review additional information or analyses provided by the company in response to clarification questions. No additional administration or review fees for ACE staff or MOH committees involved in the evaluation process will be charged to companies.

12. There will strictly be no waiver or exemption of charges or any part thereof.

LATE PAYMENT

13. All payments to ACE are due within 30 calendar days from date of invoice. A reminder will be sent to companies approximately one week before the due date. If payment is not received on time, any evidence submitted by the company will not be accepted until full payment is received. In the event of extended delays, the evaluation timelines will be revised and the topic will be rescheduled to a later DAC meeting date.

REFUNDS

14. Refunds will not be provided once the submission has been sent to the IERC for critique. Refunds will only be given for reasons that are acceptable to ACE, as described in paragraphs 15-17. In the event that a refund is provided to the company, the contractual

agreement between the company and ACE will be terminated with effect from the date of the refund.

15. If a company provides an evidence submission to ACE but then subsequently withdraws it (e.g. if the product fails to achieve regulatory approval by the Health Sciences Authority (HSA), or the company no longer intends to make the product commercially available in Singapore), ACE will not provide any refund to the company **if the submission has already been sent to the IERC** for critique.

16. If ACE identifies that an evidence submission is not fit for purpose (e.g. significant information is missing or economic model is non-functioning) before it is sent to the IERC for critique, the submission will be rejected and the payment will be refunded unless the company requests to provide a revised evidence submission. In this instance, all existing timelines for the evaluation will no longer apply and the topic will be rescheduled once the company confirms revised submission timelines.

17. If a company initially pays the charges for a full evaluation but provides a submission for an expedited evaluation instead, ACE will refund the difference in charges if the IERC has not begun its critique of the submission yet, and an expedited evaluation is considered by ACE to be appropriate. In this instance, ACE will issue a new Letter of Offer to the company to reflect the new contractual agreement between the company and ACE.

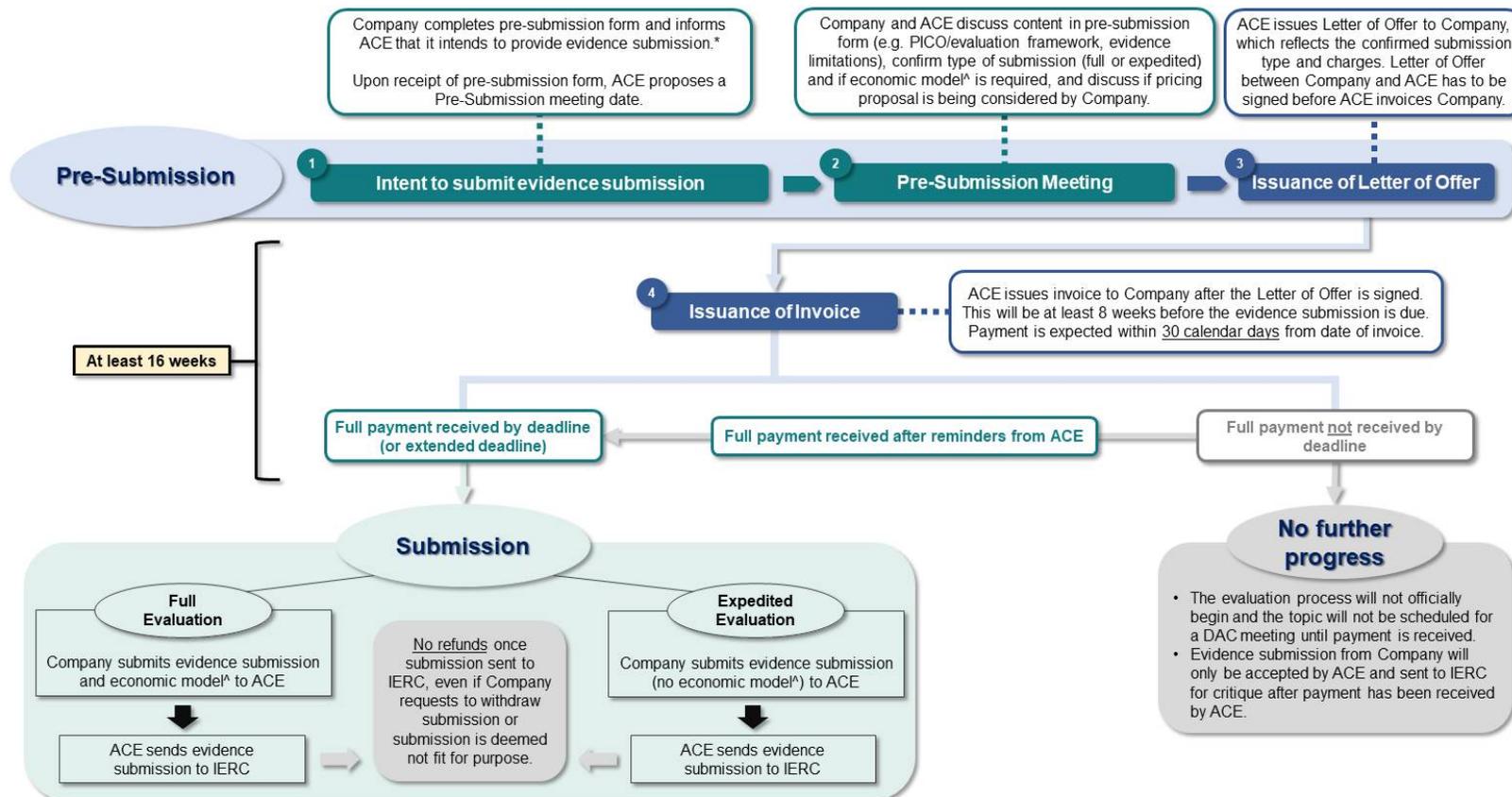
REVISION OF CHARGES

18. To conduct an independent critique of each evidence submission, charges are imposed on a cost recovery basis and therefore, may change over time. ACE may amend the charges as required, and will publish the revised charges on the ACE website. Any changes to the charges will be applied prospectively, with the company obliged to pay the charges that are in effect when the Letter of Offer is issued.

CONTACT INFORMATION

19. For any queries regarding payment, please contact Ms June Oh at june_oh@moh.gov.sg. All other enquiries relating to company evidence submissions should be directed to ace_submissions@moh.gov.sg.

Charging Procedure for Company Evidence Submissions to ACE



*Ideally in conjunction with HSA regulatory application (9-12 months before regulatory approval)

[^]Economic model refers to cost-utility analysis