[Instructional text]

Notes on the template

This document is the template for a Medical Services Advisory Committee (MSAC) Assessment Report, the objective of which is to synthesise the key information that MSAC needs to inform its deliberations.

A secondary objective is to demonstrate that a high-quality systematic review has been performed. Information requests for this purpose are predominantly in the Appendices.

This template is provided to encourage consistency between assessment reports in the underlying structure of the report, and to guide applicants and assessment groups regarding which pieces of information are most likely to be informative. However**, judgement should be used regarding whether subsections are relevant or not, and the template may be amended as required for an individual topic**. For example, if the assessment report is for a resubmission, only present sections of the report that require amendment based on feedback from MSAC.

It may be necessary to duplicate sections of the template to allow for multiple populations or interventions. Judgement is required in determining the most appropriate structure.

This page provides instructions on how the template should be interpreted. In addition to the instructions below, please be mindful that web accessibility requirements must be met for all documents that are posted on Department of Health websites.

The template includes different coloured text:

- Text written in green represents instructional text, to be deleted prior to finalising the assessment report. The beginning and end of instructional text is also indicated by the words 'Instructional text' and 'End instructional text', respectively.
- Text written in black represents proposed wording, and may contain highlighted and asterisked (*) text to indicate that an input is required.
- Cross-references to Technical Guidance (TG) sections of the *Guidelines for preparing assessments for the Medical Services Advisory Committee* (MSAC Guidelines) are presented in blue and preceded by the words 'Refer to:'. These cross-references are to be deleted prior to finalising the assessment report.

Commentary style guide

[Instructional text]

General guidance

A commentary is an evaluation of an assessment report (either applicant developed or Department contracted). The purpose of the commentary is to critically appraise the approach taken in the assessment report and identify strengths and weaknesses in the evidence or approach used. The focus of the commentary is the same as for an assessment report.

A commentary seeks to draw from the assessment report the most relevant information for decision-making. The information that is most relevant is guided by the factors that influence MSAC decision-making (see MSAC Guidelines, Preamble), and includes the comparative effectiveness, safety and cost-effectiveness of the proposed technology. Other factors that may affect the assessment of these measures are also relevant (to the extent that they will affect the interpretation of the measures). Additional factors may include, for example, consumer preferences, equity or implementation issues.

The presentation of a commentary is primarily using in-line tracked changes. It is preferable that in-line comments are appropriately placed within the assessment report. In general, brief in-line comments may be placed underneath individual paragraphs within a section of the assessment report. If longer commentary is required (such as explanations, re-analyses or comments that affect multiple sections), a brief comment can be made underneath the text in which the issue is mentioned, with a cross-reference to the longer comment. Longer commentary can be provided at the end of a subsection. For example, a re-analysis of overall survival would likely be placed at the end of the presentation of overall survival. As the re-analysis is required due to an issue with transitivity, a comment can be made in the characteristics of the evidence base, with a cross-reference directing the reader to the longer discussion. For example:

> The baseline characteristics (including some important prognostic characteristics) differ across the included single-arm studies. This is likely to impact the estimate of incremental survival in the indirect comparison. This is discussed at the end of 'Overall Survival' in Section 2A.3.

A related goal of the commentary is to identify the importance of the strengths and weaknesses of the evidence or approach taken. While each assessment report is likely to rely on assumptions and approximations, the commentary should identify those that are of concern and explain the possible impact. The commentary can then provide shorter explanations of issues that do not have a large impact on the clinical or economic estimates.

The culmination of the commentary is the executive summary.

Executive summary

The executive summary should synthesise the information that is critical for decision-making by MSAC and its sub-committees. Present data in the most logical and succinct way to get the story told. The executive summary will form the basis of the ESC advice and the MSAC public summary document. Deviations from the template instructions are permissible where justified; however, avoid changes to the heading structure used in the executive summary.

Aim to keep the executive summary brief (less than 20–30 pages).

Avoid cross-referencing to the main body of the report. If there is relevant information in the main body, provide a brief summary. For example, do not state that 'Secondary outcomes are presented in Section 2A.3'. If the results of the secondary outcomes are relevant to the interpretation of the results in the executive summary, state, for example, 'The results of the secondary outcomes are consistent with those of overall survival and progression-free survival'.

Use references sparingly and insert them as footnotes.

[End instructional text]

Commentary Executive Summary

*Application No. *XXXX – Application name (from MSAC website)*

Applicant: **[*legal name of applicant]**

Date of MSAC consideration: **MSAC *XXth Meeting, [*meeting date]**

Main issues for MSAC consideration

[Instructional text] Provide a high-level summary of the issues that are pivotal for MSAC decision-making. This summary is not intended as stand-alone information, and should only include sufficient information to understand the main issues. Further supporting detail should be included elsewhere in the executive summary. List issues in order of importance. [End instructional text]

Clinical issues:
[Instructional text]
Discuss:

- the appropriateness of any requested MBS item descriptor. For example, is the descriptor consistent with MBS policy and TGA-approved/proposed use, including class?
- the place and timing of the proposed technology in the clinical pathway
- the choice of the main comparator(s)
- the choice of cut-off or diagnostic threshold of the test
- the availability of the clinical utility standard and other suitable test options in Australia
- the reference standard for testing, if available
- caveats arising from the assessment of the primary source(s) of evidence.

[End instructional text]

Economic issues:
[Instructional text]
Discuss:

- the appropriateness of the estimate of the prevalence of the biomarker
- whether or not the economic model appropriately incorporated outcomes and costs for false-positive and false-negative test results
- whether or not the economic model appropriately incorporated any need for retesting and/or rebiopsy
- issues arising from likely actual fees charged over MBS rebate amounts and implications for out-of-pocket payments and the Extended Medicare Safety Net.

[End instructional text]

Financial issues:
[Instructional text]
Discuss:

- the appropriateness of assumptions used to estimate the numbers of eligible patients each year
- whether there are under- or overestimates, and the likely magnitude of these
- the potential for use beyond the population specified by the MBS item descriptor.

[End instructional text]

Other relevant information:
[Instructional text]
Discuss:

- any issues related to the value of knowing. This section is included if the results are likely to affect the interpretation of the key results, or influence MSAC decision-making.
- any other relevant issues that MSAC might wish to take into consideration, for example, equity issues, accessibility issues due to location restrictions, workforce issues, results of clinical trials or studies that are imminent. This section should only be included if considered sufficiently important.

[End instructional text]

1. Purpose of application

Refer to: MSAC Guidelines TG 1.1 (Request for public funding)

[Instructional text] Summarise the purpose of the application using the following format: [End instructional text]

An application requesting [*Medicare Benefits Schedule (MBS) listing OR public funding] of [*intervention name – e.g. repetitive transcranial magnetic stimulation (rTMS)] for [*indication – e.g. treatment of antidepressant medication-resistant major depressive disorder (MDD)] was received from the [*legal name of applicant] by the Department of Health.

OR

The codependent application requested:

- Medicare Benefits Schedule (MBS) listing of [*intervention name – e.g. optical coherence tomography (OCT) for the determination of patient eligibility and for efficacy assessment of a single treatment with ocriplasmin (JETREA®)]; and
- Pharmaceutical Benefits Scheme (PBS) Authority Required listing of [*medicine name – e.g. ocriplasmin for the treatment of vitreomacular traction (VMT) including those with full-thickness macular hole (FTMH)].

2. Background

[Instructional text]

Summarise any relevant background to the application, such as prior applications for the same or similar technologies. Example text:

MSAC has not previously considered single-balloon enteroscopy for the investigation of gastrointestinal bleeding.

MBS items 30680, 30682, 30684 and 30686 for double-balloon enteroscopy were introduced on the MBS from 1 July 2007.

Refer to: MSAC Guidelines TG 4 (History of MSAC submissions for the health technology)

If the proposed technology has been previously considered by MSAC (for this or a similar indication), summarise the previous MSAC considerations. Include other relevant MSAC considerations, if informative.

Summarise the key matters of concern from previous considerations using the standard table format below (Table 1) and include hyperlinks to key relevant published PSDs.

[End instructional text]

Table 1 Summary of key matters of concern

Component	Matter of concern	How the current assessment report addresses it
[Identify the relevant section of the previous assessment report, e.g. comparator, clinical claim, economic evaluation]	[Identify matter of concern. Cite paragraph of the MSAC PSD (use abbreviated referencing in tables)]	[*Addressed/Not adequately addressed/not addressed] [Comment and/or cross-reference to where matter is addressed in the executive summary or main body of the report]
Example text: Clinical place in therapy	Example text: MSAC suggested the descriptor should reinforce that psychotherapy must have been previously trialled (PSD, p.2).	Example text: Addressed. Restriction amended to reflect MSAC comments.
Example text: Clinical effectiveness	Example text: MSAC noted there was other available evidence that could be informative on the relative effectiveness that was not presented in the resubmission, including the EUnetHTA 2017 and Ontario Health 2016 reports (PSD, p.3)	Example text: Addressed. The efficacy results from EUnetHTA 2017 are now applied in the economic modelling as this is the more recent of the two reviews requested to be reviewed by MSAC.

EUnetHTA = European Network for Health Technology Assessment; MSAC = Medical Services Advisory Committee; PSD = Public Summary Document. [Define all abbreviations used in the table]

3. Prerequisites to implementation of any funding advice

[Instructional text]

State whether the proposed technology includes a therapeutic good that requires TGA approval. Provide the status of the TGA process (including date or estimated date of inclusion on the ARTG and the relevant ARTG numbers where available).

State any other prerequisites, for example, a quality assurance program for a pathology test, a licensing program for an imaging technology, or a funding arrangement that needs to be established because the proposed technology is not suitable for any current source of public funding. Identify where each such prerequisite is still to be met.

[End instructional text]

4. Proposal for public funding

Refer to: MSAC Guidelines TG 3 (Proposed funding arrangements)

[Instructional text]

State the applicant's post-PASC proposal for public funding.

State whether the proposed technology (or technologies) is new or a variation of an existing technology. If a description of the technology is necessary, this should be brief.

If public funding is sought via the MBS, state whether the proposal intends to use existing MBS items, amend existing MBS items or create new MBS items (or a combination of these options).

For each MBS item, provide its group, descriptor, fee, benefits and explanatory notes. Ensure that amendments are clearly presented (Table 2).

[End instructional text]

Table 2 Presentation of an existing, amended or newly proposed MBS item

Category <*Insert proposed category no.> – <*INSERT CATEGORY NAME>
MBS item *XXXX <*Insert intervention name> <*Specify any restrictions on use, e.g. patient characteristics to be satisfied, limits on frequency of use, limits on who can provide the item, or where it can be provided> <*Specify any relevant explanatory notes>
Fee: <*Insert proposed MBS fee>

[Instructional text]

For all funding proposals (MBS and non-MBS applications), describe and explain any restrictions based on clinical indications or prior interventions. Identify any specialty groups who would deliver the proposed technology, and, if relevant, whether the proposed technology should be restricted to any particular specialists or credentialed practitioners. State whether there are requirements of geography, facilities or location of delivery (e.g. limited to a hospital setting or to institutions with specific accreditation or licensing, or requiring specific equipment).

For investigative technologies, include whether the item should be pathologist determinable, or whether it should be limited to approved laboratories.

Provide the proposed fee, and comment on how it compares to existing similar items.

Summarise any key issues with the proposed descriptor (e.g. not consistent with the trial, TGA registration or clinical guidelines).

Examples:

The application proposed that the MBS item numbers for DBE be amended to replace the term ‘double balloon enteroscopy’ with ‘balloon-assisted enteroscopy’ so that the same MBS items may be used for either DBE or SBE.

MBS items for capsule endoscopy (CE) also need to be amended to cross-reference balloon enteroscopy (or the MBS item numbers) rather than DBE.

[End instructional text]

5. Population

Refer to: MSAC Guidelines TG 2.1 (Population)

[Instructional text]

State whether there is more than one PICO set (usually required when the proposed technology is used across different populations or for different indications).

For each PICO set (each unique population/indication pair) state whether the proposed technology would be used:

- in place of a current technology (as an alternative or as a replacement)
- in addition to a current technology (before, after, concomitantly or displacement)
- where no current technology is publicly funded (available, but not funded)
- where no current technology is available (e.g. 'best supportive care' or 'watchful waiting')
- in the context of a rare disease or circumstance (e.g. an orphan or minority population).

For each PICO set, summarise where the proposed technology fits into the clinical management algorithm according to the applicant's post-PASC proposal for public funding. The summary should include the patient's clinical pathway up to the point where the proposed technology is appropriate.

If the use of medical services following the use of the proposed technology will change, summarise the downstream impacts on resource use (e.g. displaced therapies or avoided tests).

State whether the assessment report addresses the requirements of the confirmed PICO.

[End instructional text]

6. Comparator

Refer to: MSAC Guidelines TG 2.3 (Comparator)

[Instructional text]

Describe the comparator as specified by the applicant post-PASC.

State whether the post-PASC comparator is appropriate. If not, what is the preferred comparator and why?

State whether and how the comparator is currently funded (e.g. public or private hospital, MBS, other funding source). If the comparator is MBS listed, provide the MBS item number(s), descriptor(s) and date(s) of listing.

[End instructional text]

7. Characteristics of the evidence base

[Instructional text]

Note. There are no particular TGs in the MSAC Guidelines that request this type of summary. This is the culmination of the methodological appendices (2–5), and the information should be drawn from the study profiles in Appendix B.

Tabulate the primary source(s) of evidence (see Table 3 and Table 4). Indicate which sources provide evidence of safety, effectiveness or both. For each source, identify the type of study (e.g. randomised trials, indirect comparison, nonrandomised studies), the key outcome(s) relevant to the evaluation and the overall risk of bias (relevant to the key outcomes). Indicate which sources have been used in the economic evaluation.

[End instructional text]

Table 3 Key features of the included evidence (example for a therapeutic technology)

References	N	Design/duration	Risk of bias	Patient population	Outcome(s)	Use in modelled evaluation
[*proposed intervention vs comparator]						
Jones 2010	225		*Low*			Not used
Smith 2012	310		*High*			Not used
Brown 2005	75		*Low*			Not used
Meta-analysis	410	Included Jones 2010 and Brown 2005; sub-group analysis; assessed overall survival				Survival gain
etc.						
etc.						

DB = double blind; MC = multicentre; OL = open label; OS = overall survival; PFS = progression-free survival; R = randomised. [Define all abbreviations used in the table]

Table 4 Key features of the included evidence (example for an investigative technology)

Criterion	Type of evidence supplied	Extent of evidence supplied			Overall risk of bias in evidence base
Accuracy and performance of the test (cross-sectional accuracy)	[Describe study designs used to assess test accuracy]	☐	k=	n=	[use QUADAS-2 risk of bias tool]
Prognostic evidence (longitudinal accuracy)	[Comparison of outcomes in patients receiving *usual care*, conditioned on the presence or absence of biomarker-positive status]	☐	k=	n=	[could use QUIPS risk of bias tool]
Change in patient management	[Evidence to show that test result guides decisions about treatment or alters behaviour]	☐	k=	n=	[could use Cochrane risk of bias tool]
Health outcomes	[Evidence to show that the changes in management or behaviour affect health outcomes]	☐	k=	n=	[could use Cochrane risk of bias tool]
Predictive effect (treatment effect variation)	[Comparison of outcomes in patients with and without the biomarker who receive the treatment of interest, or usual care]	☐	k=	n=	[could use Cochrane risk of bias tool]
Other		☐	k=	n=	

k=number of studies, n=number of patients. [Define all abbreviations used in the table]

8. Comparative safety

Refer to: MSAC Guidelines TG 7 (Safety of therapeutic technologies)

Refer to: MSAC Guidelines TG 14 (Safety of investigative technologies)

[Instructional text]

Tabulate the main safety results in a way that permits a comparison of the proposed technology and the main comparator. Safety results relevant for inclusion in the executive summary are those that support or diminish the clinical claim. Usually these will be safety results that are severe (with a substantial impact on patients) or frequent, or where the safety profile of the proposed technology differs from that of the comparator.

For investigative technologies, present the direct harms of the test. Separately summarise the consequent harms of testing (i.e. those mediated through subsequent changes to clinical management).

State key limitations of the evidence and provide an interpretation of their impact on the certainty of the results.

State whether the proposed technology is safer, of similar safety or less safe than clinical management without it.

[End instructional text]

9. Comparative effectiveness

Refer to: MSAC Guidelines TG 6 (Effectiveness of therapeutic technologies)

Refer to: MSAC Guidelines TG 10 (Direct from test to health outcomes evidence)

Refer to: MSAC Guidelines TG 11 (Linked evidence – test accuracy)

Refer to: MSAC Guidelines TG 12 (Linked evidence – change in management)

Refer to: MSAC Guidelines TG 13 (Linked evidence – health outcomes)

[Instructional text]

Tabulate the main effectiveness results in a way that permits a comparison of the proposed technology and the main comparator. Where appropriate, provide meta-analysed results. For time-to-event outcomes, graphical presentations may be informative. Effectiveness results relevant for inclusion in the executive summary are those that are derived using high-quality evidence and which support or diminish the clinical claim. Usually these will be effectiveness results that are most patient relevant, or that reveal similarity or dissimilarity to the main comparator.

The selection of results for the executive summary should provide a clear picture of the comparative effectiveness but not repeat findings. After providing the most important results, it is sufficient to state whether the secondary or alternative outcomes are consistent with the primary outcomes.

Effectiveness results for therapeutic technologies include the primary outcomes of studies, and key secondary patient-relevant outcomes.

Effectiveness results for investigative technologies will depend on the approach taken:

- For direct from test to health outcomes evidence, report patient-relevant outcomes as for therapeutic technologies above. Results should be separated for test-positive and test-negative patients, where possible.
- For a linked evidence approach, briefly report the test accuracy, prevalence and relevant estimates of accuracy as applied to the target Australian population (e.g. positive predictive value, negative predictive value). Present results for change in management. Results for health outcomes are reported in a similar way to outcomes of a therapeutic technology; however, results should be separated by test-positive and test-negative patients. In addition, results for false positives and false negatives may be relevant.

- For the assessment of investigative technologies, discuss the clinical utility (net health benefit or harm) incorporating all of the relevant steps. Where this is uncertain, describe these uncertainties.

State key limitations of the evidence, with reference to the internal validity of the evidence (bias or confounding), the approach to generating the evidence (transitivity for indirect comparisons of studies), translations of the evidence (if surrogate outcomes have been used and translated to patient relevant outcomes), and the applicability of the evidence to the Australian setting. Provide an interpretation of the impact any limitations of the evidence may have had on the certainty of the evidence. Limit the key limitations to those that are most likely to impact the estimates of the results.

Provide a summary of the interpretation of the clinical evidence including the direction of effect, the size of effect and the level of confidence MSAC can have in this evidence.

State whether the proposed technology is more effective, of similar effectiveness or less effective than clinical management without it.

[End instructional text]

Clinical claim

Refer to: MSAC Guidelines TG 8 (Interpretation of the therapeutic evidence)

Refer to: MSAC Guidelines TG 16 (Interpretation of the investigative evidence)

[Instructional text] Summarise whether the evidence supports the clinical claim, and thus whether the presented form of economic evaluation is appropriate and supported. [End instructional text]

10. Economic evaluation

[Instructional text]

State the type of economic analysis.

Refer to: MSAC Guidelines TG 17 (Overview and rationale of the economic evaluation)

Describe the structure of the model and provide a brief overview (tabulated; see Table 5) of the model parameters.

If no economic evaluation was performed, explain why and summarise the alternative approach taken.

Refer to: MSAC Guidelines TG 26 (Cost-minimisation approach)

If the assessment of the proposed technology has taken a cost-minimisation approach, report the costs for the proposed health technology and the comparator. Present the costs separated into direct costs associated with the use of the technology, and downstream costs or cost offsets. Identify where costs are incurred across different funding mechanisms (e.g. private costs, MBS costs, public hospital costs). Summarise uncertainties associated with the cost comparison.

[End instructional text]

Table 5 Summary of the economic evaluation

Component	Description	MSAC Guidelines Reference
Perspective	[*e.g. Health care system perspective]	TG 17.3
Population	[For multi-indication models, specify the different populations (or subgroups) modelled. For example, for testing of heritable diseases, index cases, and adult and child relatives may be modelled]	TG 19
Prior testing	[*specify the tests required to determine the population in the model]	TG 19
Comparator	[*comparator]	TG 17.2
Type(s) of analysis	[*e.g. cost-effectiveness analysis, cost-utility analysis]	TG 17.5
Outcomes	[*e.g. events avoided, life-years gained, quality-adjusted life years]	TG 21
Time horizon	[*e.g. [x] days/months/years in the model base case (vs [y] weeks/years in the key trial(s))]	TG 18.2
Computational method	[*e.g. cohort expected value, Markov, partitioned survival analysis, microsimulation, discrete event simulation]	TG 18.3
Generation of the base case	[*e.g. trial based or modelled. [If modelled, summarise the steps undertaken in the economic analysis]	TG 17.6
Health states	[If a state transition model is used, state the health states included. This could also include decision tree terminal states or events modelled in a discrete event simulation.]	TG 18
Cycle length	[*x days/weeks/months/years]	TG 18.3
Transition probabilities	[Where different data sources are used to inform different transition probabilities, e.g. baseline event rate, treatment effect, secondary transition probabilities, describe the source(s) of each key model input. For investigative technologies, the sources of data used to inform additionally relevant inputs, such as prevalence, accuracy and change in management, should also be summarised. Indicate if the data required translation for use in the economic analysis.]	TG 20
Discount rate	[*e.g. 5% for both costs and outcomes]	TG 17.4
Software	[*e.g. Excel, @RISK, TreeAge Pro]	TG 18.3

[Define all abbreviations used in the table]

[Instructional text] A commentary for an ADAR may present an alternative base-case analysis alongside the ADAR base-case analysis. Explain why an alternative base-case is recommended in the commentary. [End instructional text]

Refer to: MSAC Guidelines TG 24 (Results of the base-case economic evaluation)

[Instructional text] If possible, present a stepped economic analysis for the base-case results of the economic evaluation (see Table 6 and Table 7). [End instructional text]

Table 6 Results of the stepped economic analysis (therapeutic example)

Step	[*Proposed health technology]	[*Main comparator]	Increment	ICER
Step 1 – Comparative study data (as presented in Section 2); Setting: [*trial setting]; Time horizon: [*trial follow-up]				

Step	[*Proposed health technology]	[*Main comparator]	Increment	ICER
Costs	$[A]	$[B]	$[A – B]	
Outcome 1 (surrogate outcome)	[C]	[D]	[C – D]	$[A – B]/[C – D]
Step 2 – Study evidence transformed from surrogate to clinical outcome				
Costs	$[A]	$[B]	$[A – B]	
Outcome 1 (clinical outcome)	[E]	[F]	[E – F]	$[A – B]/[E – F]
Step 3 – Study evidence transformed to clinical outcome and translated to the Australian population and/or Australian setting (may need multiple steps)				
Costs	$[A]	$[B]	$[A – B]	
Outcome 2	[E]	[F]	[E – F]	$[A – B]/[E – F]
Step 4 – Study evidence transformed to clinical outcome, translated to the Australian population/setting, and extrapolated to the appropriate time horizon				
Costs	$[G]	$[H]	$[G – H]	
Outcome 2	[I]	[J]	[I – J]	$[G –H]/[I – J]
Step 5 – Study evidence transformed to clinical outcome, translated to the Australian population/setting, extrapolated and with additional assumptions or modelled information				
Costs	$[K]	$[L]	$[K – L]	
Outcome 2	[M]	[N]	[M – N]	$[K –L]/[M – N]
Step 6 – Study evidence translated to clinical outcomes, the Australian population/setting, extrapolated, with additional modelling, and transformed into a relevant health outcome (e.g. QALYs)				
Costs	$[K]	$[L]	$[K – L]	
Outcome 3 (QALYs)	[O]	[P]	[O – P]	$[K –L]/[O – P]

ICER = incremental cost-effectiveness ratio; QALY = quality-adjusted life year. [Define all abbreviations used in the table]

Note: Multiple outcomes may be informative for MSAC decision making-within each step.

Table 7 Results of the stepped economic analysis (investigative example)

Step	[*Proposed health technology]	[*Main comparator]	Increment	ICER
Step 1 – Comparative diagnostic accuracy, as applied to the prevalence in the eligible Australian population Time horizon: time to reach a diagnosis				
Costs	$[A]	$[B]	$[A – B]	
Total correct diagnoses	[C]	[D]	[C – D]	$[A – B]/[C – D]
Step 2 – Incorporation of repeat or confirmatory testing, which may affect final diagnostic conclusions Time horizon: time to reach a diagnosis				
Costs	$[E]	$[F]	$[E – F]	
Total correct final diagnoses	[G]	[H]	[G – H]	$[E – F]/[G – H]
Step 3 – Uptake of treatment, or other change in clinical management, by final test result Time horizon: time to treatment allocation decision				
Costs	$[I]	$[J]	$[I – J]	
Appropriate management allocation	[K]	[L]	[K – L]	$[I – J]/[K – L]
Step 4 – Incorporation of effectiveness of treatment (e.g. survival benefit) translated to the Australian population and/or setting, and extrapolated to the appropriate time horizon (may need multiple steps) Time horizon: appropriate time horizon to capture differences in costs and outcomes due to changes in treatment allocation decisions (e.g. lifetime)				
Costs	$[M]	$[N]	$[M – N]	
Life years gained	[O]	[P]	[O – P]	$[M – N]/[O – P]
Step 5 – Outcomes transformed into a relevant health outcome (e.g. QALYs)				
Costs	$[M]	$[N]	$[M – N]	
QALYs	[Q]	[R]	[Q – R]	$[M – N]/[Q – R]

ICER = incremental cost-effectiveness ratio; QALY = quality-adjusted life year. [Define all abbreviations used in the table]

Note: Multiple outcomes may be informative for MSAC decision-making within each step.

[Instructional text] Where the proposed health technology is a heritable genetic test, in addition to a table that presents step-wise incorporation of key assumptions regarding change in management due to testing and transformation of outcomes (i.e. Table 7), present a table that explores alternate listing scenarios around the base-case analysis, where testing is limited to, for example, affected cases only, affected cases and their first-degree relatives only, etc. (Table 8). [End instructional text]

Table 8 Alternate scenarios exploring which cohorts of relatives are eligible for proposed heritable genetic testing

Parameter	[*Proposed health technology]	[*Main comparator]	Increment	ICER
Affected cases only				
Costs QALYs No. positive affected cases identified No. positive relatives identified No. with appropriate management				
Affected cases and first-degree relatives				
Costs QALYs No. positive affected cases identified No. positive relatives identified No. with appropriate management				
Affected cases and first- and second-degree relatives				
Costs QALYs No. positive affected cases identified No. positive relatives identified No. with appropriate management				

ICER = incremental cost-effectiveness ratio; QALY = quality-adjusted life year. [Define all abbreviations used in the table]

Note: Multiple outcomes may be informative for MSAC decision-making – examples have been presented.

[Instructional text] Present the overall results of the base case (Table 9). [End instructional text]

Table 9 Results of the economic evaluation

Parameter	[*Proposed health technology]	[*Main comparator]	Increment
Costs	${*}	${*}	${*}
Life years	{*value}	{*value}	{*value}
QALYS	{*value}	{*value}	{*value}
Incremental cost per life year gained			**${*} or dominant/dominated**
Incremental cost per QALY gained			**${*} or dominant/dominated**

QALY = quality-adjusted life year. [Define all abbreviations used in the table]

Refer to: MSAC Guidelines TG 25 (Uncertainty analysis: model inputs and assumptions)

[Instructional text] Present the key drivers of the model that are uncertain (Table 10). Drivers may include inputs and translation issues. Rate the impact on the ICER as high or moderate. Keep the text in the tables brief. If further explanation of the key drivers is required, provide this in text. [End instructional text]

Table 10 Key drivers of the model

Description	Method/Value	Impact [If relevant per rows below, add:] Base case: $xx,xxx/QALY gained
Extrapolation	Treatment effect continued beyond [*x]-month trial period for up to [*xx] years OR Point of extrapolation [*before/after] time when observed data became unreliable as a result of [*e.g. small numbers of patients remaining event-free]	*High, favours [*proposed technology]* [If relevant, consider adding:] *Use of [*xx approach] increased the ICER to *$xx,xxx/QALY gained.* [State the base-case ICER in the header row.]
Utilities	High values for model health states taken from [*literature] and no disutility for adverse events	*High, favours [*proposed technology]* [If relevant, consider adding:] *Use of [*xx utilities] increased the ICER to *$xx,xxx/QALY gained.* [State the base-case ICER in the header row.]
etc.		

ICER = incremental cost-effectiveness ratio; QALY = quality-adjusted life year. [Define all abbreviations used in the table]

[Instructional text]

Present key concerns with the economic evaluation. These may be the key drivers of the model. For example:

- If the time horizon is a key issue, consider presenting a trace of ICER over time, but only present this in the executive summary if it will be informative for MSAC decision-making (e.g. consider whether it is the time horizon or the extrapolation that is a key issue).
- If the utilities or costs are a key issue, consider presenting an abbreviated disaggregated costs/outcomes table to show the impact.
- Where relevant, consider including information that highlights inconsistencies or differences between the model and clinical data (e.g. a table comparing the number of events avoided in the model compared with the clinical trial data; graphs with an overlay of the Kaplan–Meier plot and the modelled extrapolations; or disaggregated costs and outcomes).
- Where relevant, describe the extent to which the model includes out-of-pocket expenses.

Present and justify key sensitivity analyses (Table 11).

For example: [End instructional text]

The results of key [*univariate/multivariate] sensitivity analyses are summarised below.

[Instructional text] Only present key sensitivity analyses that are pivotal for MSAC decision-making in the executive summary (i.e. concentrate on parameters with which there are issues and which have an impact on the ICER). This table should generally be no more than half a page. A more comprehensive table should be presented in the main body of the assessment report. Consider presenting 1 or 2 realistic multivariate sensitivity analyses that assess the key issues. [End instructional text]

Table 11 Sensitivity analyses

Analyses	Incremental cost	Incremental QALY	ICER
Base case	**${*}**	**{*value}**	**${*}**
Time horizon (base case 30 years)			
20 years	${*}	{*value}	${*}
10 years	${*}	{*value}	${*}
etc.			

ICER = incremental cost-effectiveness ratio; QALY = quality adjusted life year. [Define all abbreviations used in the table]

11. Financial/budgetary impacts

Refer to: MSAC Guidelines TG 27 (Use of the health technology in practice)

[Instructional text] Explain the approach used to estimate the uptake of the proposed technology (e.g. epidemiological approach, market-based approach). [End instructional text]

The financial implications to the [*MBS/other funding source] resulting from the proposed listing of [*proposed health technology] are summarised in Table 12.

[Instructional text] The financial implications are presented over 6 years (Table 12). *If the proposed funding source is the MBS, consider presenting the net financial implications in financial years. In this case the table should present the year as "FY 20XX-XX" rather than "20XX".* Amend table content as relevant. [End instructional text]

Table 12 Net financial implications of [*proposed health technology] to the [*relevant funding program]

Parameter	Year 20XX	Year 20XX	Year 20XX	Year 20XX	Year 20XX	Year 20XX
Estimated use and cost of the proposed health technology						
Number of people eligible for [*proposed health technology]						
Number of people who receive [*proposed health technology]						
Number of services of [*proposed health technology] (if more than one per person)						
Cost to the [*relevant funding program] (with appropriate copayments excluded)						
Change in use and cost of other health technologies						
Change in use of [*comparator]						
Change in use of [*other affected health technologies]						
Net change in costs to the [*relevant funding program] (with appropriate copayments excluded)						
Net financial impact to the [*relevant funding program]						

[Define all abbreviations used in the table]

[Instructional text]

The summary of financial implications should primarily focus on the implications to the funding sources (e.g. MBS, National Blood Authority).

Present the following (adapted if necessary):

- The average cost of the proposed technology per patient <per year/per course> is: $X.
- The average frequency of use of the proposed technology is: X <per year/per lifetime>.
- The average out-of-pocket cost per patient <per year/per course> is: $X.

Note that the out-of-pocket cost per patient includes both the estimated copayments and the additional costs above the funded amount.

If a service is primarily out-of-hospital, a separate analysis of the financial implications to the Extended Medicare Safety Net will be required.

If there is additional relevant information that should be taken into account in the financial implications (e.g. cost impacts on other government health budgets, patient costs), mention these here and be guided by the Department as to what data would be expected.

[End instructional text]

12. Other relevant information

Refer to: MSAC Guidelines TG 5 (Approach to assessment)

Refer to: MSAC Guidelines TG 28 (Value of knowing)

[Instructional text] In addition to a clinical claim relating to health outcomes, investigative technologies may (uncommonly) make a claim of 'value of knowing'. For an investigative technology that results in no, minimal or uncertain change in management, where the key benefit relates to the value of knowing, tabulate the key proposed value of knowing benefits and harms associated with the use of the proposed test (Refer to: TG 28.2). Key results are those that are quantitative and supported by evidence. [End instructional text]

Refer to: MSAC Guidelines TG 29 (Other relevant considerations)

[Instructional text] Summarise any other relevant factors (e.g. ethical, legal, social, equity) as appropriate, or identify as 'Nil'. [End instructional text]

13. Committee-in-confidence information

[Instructional text] Include Committee-in-confidence information if relevant, or identify as 'Nil'. [End instructional text]