MEDICAL SERVICES ADVISORY COMMITTEE REAPPLICATION TEMPLATE

Most applicants planning to lodge a revised Applicant Developed Assessment Report (ADAR) for MSAC consideration following a 'not supported' outcome should complete this template. However, check with the department (MSAC.secretariat@health.gov.au) whether this template is suitable if:

A. your previous application was considered by MSAC before April 2025, or you plan to ask for a Department Contracted Assessment Report (DCAR)

B. you were advised to use this template by MSAC or the department, for example at a post-MSAC debrief meeting or in the PSD for your previous application, but circumstances have changed. For example:
   - you are proposing changes to the PICO in addition to any changes flagged by MSAC in the previous PSD
   - the proposed funding source has changed
   - the applicant has changed
   - regulatory matters have arisen
   - it has been more than two years since MSAC considered the previous application
   - there are other substantial changes not previously flagged with MSAC or the department.

Seeking advice from the department will help avoid any delays with your reapplication.

Instructions for completion and lodgement

This Reapplication Template is comprised of questions about proposed funding and regulatory information, along with two tables for completion. The first table seeks information on how applicants plan to address, in the revised ADAR, key matters of concern outlined by MSAC in the Public Summary Document (PSD) for the previous application(s). It mirrors Table 2, in part 1.1 of the ADAR Assessment Report Template.

The second table seeks information on any changes to the PICO set compared to the PICO in the previous ADAR considered by MSAC. This table is similar to Table 3, in part 1.6 of the ADAR Assessment Report Template. Do not duplicate between tables—If PICO changes resulted from matters of concern raised by MSAC, note this when completing Table 2. If there are no changes to the PICO set, check the relevant radio box and leave Table 2 blank.

Once completed, sign the declaration. Upload the Reapplication Template to the Health Products Portal (HPP) when you submit your Notice of Intent to lodge an ADAR. Guidance is available on the MSAC website.

Publication

For ADARs found suitable to proceed, the department will publish the completed Reapplication Template on the MSAC website to facilitate consultation. If you have included information that you consider to be confidential, highlight the relevant text and provide your reasons for why this text is confidential. The department will consider your request and will redact information that it agrees is confidential prior to publication.

How the department will use the information provided in the completed Reapplication Template

The department will review the completed Reapplication Template to help determine:

1. If the proposed ADAR will attempt to address all the matters of concern raised by MSAC in respect of the previous application(s) and is therefore suitable for lodgement. If you do not intend to address all the matters of concern raised by MSAC, please discuss this with the department before proceeding.

2. If there are outstanding matters that the applicant and department need to discuss and resolve before lodgement of an ADAR.

3. Whether the applicant needs to complete a new MSAC Application Form before considering lodgement of an ADAR. This can be avoided by checking with the department before submitting a reapplication template if one or more of the circumstances listed in points A and B above apply.

If the department has concerns about your proposed ADAR or forms the view that a new MSAC Application Form is required, we will discuss this with you and provide advice on options going forward. Providing accurate information in this template will reduce the risk that the department finds a lodged ADAR unsuitable to proceed to MSAC.

MSAC REAPPLICATION TEMPLATE

Reapplication Name:	
Previous application number	Insert the MSAC application number allocated to the previous related application that was considered by MSAC
Name of previous application	Insert the name of the previous related application that was considered by MSAC

A. Funding Source

1. **Please check the box that corresponds with the program through which the health technology would be funded:**

☐ Medicare Benefits Schedule (MBS). Please:

a) Upload an in principle Statement of Clinical Relevance[1] when uploading this template.
b) Note in Table 2 below, any changes to the proposed MBS item(s) compared to the previous ADAR.

☐ National Blood Agreement.

☐ National Health Reform Agreement Addendum (high-cost, highly specialised therapies).

☐ National Diabetes Services Scheme.

☐ Other. Please specify the funding program:

2. **Has the funding source changed compared to your previous application?**

☐ No

☐ Yes. If you have not already done so, please contact MSAC.secretariat@health.gov.au to discuss whether a new MSAC Application Form needs to be completed.

If continuing with this template, please outline in the box below:

a. What is the reason for this change?

b. What discussions, if any, have you had with the area of the department responsible for the proposed funding source? Who have you liaised with?

[1] The in principle Statement of Clinical Relevance demonstrates 'in principle' support for the proposed service. This must be from the most relevant professional medical/health group (i.e., an official college or society) that represents practitioners who would **perform** the proposed services, and (in the case of investigative technologies only) practitioners who would **request** the proposed service.

B. Regulatory Information

1. Does your proposed service or technology involve (check as many as applicable):

- ☐ the use of a medical device, *in-vitro* diagnostic test, radioactive tracer, or any other type of therapeutic good? Please complete the section titled B1: ARTG Listing.
- ☐ a service or laboratory requiring accreditation by the National Association of Testing Authorities (NATA)? Please complete the section titled B2: NATA Accreditation.
- ☐ an MBS item descriptor that refers to a specific radiopharmaceutical or a set of radiopharmaceuticals? Please complete the section titled B3: Radiopharmaceuticals.
- ☐ None of the above. Proceed to the Other information section.

B1: ARTG Listing

If your service or technology involves the use of a therapeutic good, it cannot receive public funding until the therapeutic good has market authorisation (unless it is exempt). Market authorisation usually means a listing on the Australian Register of Therapeutic Goods (ARTG).

The department will not progress a Notice of Intent or ADAR for a reapplication involving the use of a therapeutic good until you provide evidence that:

- the therapeutic good is listed on the ARTG; or
- you (or the relevant sponsor) have commenced the TGA registration/listing process; or
- the therapeutic good is exempt.

For further information refer to the Regulatory Processes information on the MSAC website.

2. Has the proposed health technology been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?

- ☐ No (Go to question 4)
- ☐ Yes. Please state the ARTG ID, TGA approved indication(s) and TGA approved purpose:

ARTG ID:	
TGA approved indication(s):	
TGA approved purpose:	

3. Is the intended purpose in this reapplication the same as the intended purpose of the ARTG listing?

- ☐ Yes. Go to the next applicable section (B2: NATA Accreditation; B3: Radiopharmaceuticals; or Other Information).
- ☐ No. Please explain the differences below, then proceed to the next applicable section (B2: NATA Accreditation; B3: Radiopharmaceuticals; or Other Information)

4. **Is the therapeutic good classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?**

   ☐ No

   ☐ AIMD

   ☐ Class III

5. **Is the therapeutic good to be used in the service exempt from the regulatory requirements of the *Therapeutic Goods Act 1989*?**

   ☐ No

   ☐ Yes. Please attach supporting documentation regarding the nature of the exemption, then proceed to the next applicable section (B2: NATA Accreditation; B3: Radiopharmaceuticals; or Other Information).

6. **Is the therapeutic good classified by the TGA as for Research Use Only (RUO)?**

   ☐ No

   ☐ Yes.

7. **Is the therapeutic good in the process of being considered for inclusion by the TGA?**

   ☐ No. The department will not progress a Notice of Intent or ADAR until you show evidence that you (or the relevant sponsor) has commenced the TGA process.

   ☐ Yes. Please provide the TGA Application ID and submission date:

Application ID:	
Submission Date:	

8. **Is the intended purpose in this reapplication the same as the intended purpose in the application for inclusion in the ARTG?**

   ☐ Yes

   ☐ No. Please explain the differences:

B2: NATA Accreditation

Where applicable, laboratories and other investigative service providers must be accredited by NATA. The scope of NATA accreditation must capture the service for which reimbursement is being sought.

Please provide details of NATA accreditation, clearly demonstrating that the services or technologies included in your MSAC reapplication are in-scope of the accreditation. Where accreditation is not yet in place, provide documentation demonstrating that the accreditation process is underway. Provide anticipated timeframes for the NATA accreditation decision.

B3: Radiopharmaceuticals

Please refer to the Framework for the MSAC assessment of radiopharmaceuticals available on the MSAC website.

1. **Does the framework require you to provide additional information as part of your MSAC reapplication?**

   ☐ No. (Go to Other Information)

   ☐ Yes.

2. **Was the required information provided in the previous related application?**

   ☐ No. (Please upload the required information at the same time as you upload this template).

   ☐ Yes.

3. **Is the information in the previous related application still accurate and current?**

   ☐ No. Please update the information and upload at the same time as you upload this template.

   ☐ Yes. (Go to Other Information)

Other Information

Please advise us if there is anything relevant to MSAC's consideration of the reapplication that is not addressed elsewhere in this template. For example, proposed major changes to the ADAR unrelated to matters of concern raised by MSAC; or the health technology is subject to a recall or other regulatory action. You can also list here any additional organisations, experts, or other stakeholders for consultation.

Publication

If your ADAR is approved to proceed to MSAC, the department will publish your completed Reapplication Template in its entirety on the MSAC website (including Tables 1 & 2). This is to facilitate targeted and public consultation on the reapplication.

If the completed Reapplication Template (including Tables 1 & 2) includes information that you consider to be confidential, highlight the relevant text/data using yellow highlighter. Provide your reasons for why this information should be treated as confidential. You can provide your reasons by inserting a comment in the word document, next to the highlighted text, or include your rationale in the text box below:

☐ I agree that the completed Reapplication Template may be published on the MSAC website in its entirety.

☐ I have identified confidential information in my completed Reapplication Template and request that this information be redacted prior to publication.

NOTE: If this option is checked, the department will review the information marked as confidential. If agreed, the department will redact this information prior to publication of the Reapplication Template. If the department does not agree with the requested redactions, we will contact you to discuss.

Please complete tables 1 and 2 below and sign the declaration before submitting

Table 1: Summary of key matters of concern

Instructional and sample text – please delete from completed template

COMPONENT	MATTER OF CONCERN	HOW MATTER WILL BE ADDRESSED IN ADAR
Identify the relevant section of the previous assessment report. For example: 'comparator', 'clinical claim', 'economic evaluation' etc.	Identify matter of concern raised by MSAC. Cite the paragraph of the MSAC PSD (use abbreviated referencing in tables).	Addressed/partially addressed/not addressed. Provide comments outlining how this matter will be addressed in the ADAR. If available, please also provide a cross-reference to where this will be addressed in the ADAR.
Clinical place in therapy	MSAC suggested the MBD item descriptor should reinforce that psychotherapy must have been previously trialled (PSD, p.2, para 12).	**Addressed**. Restriction will be amended to reflect MSAC comments.
Clinical effectiveness.	MSAC noted there was other available evidence which could be informative on the relative effectiveness that was not presented in the reapplication, including the EUnetHTA 2017 and Ontario Health 2016 Reports (PSD, p.3, para 17).	**Addressed** The efficacy results from EUnetHTA 2017 will be applied in the economic modelling, as this is the more recent of the two reviews requested to be reviewed by MSAC.
COMPONENT	**MATTER OF CONCERN**	**HOW MATTER WILL BE ADDRESSED IN ADAR**

COMPONENT	MATTER OF CONCERN	HOW MATTER WILL BE ADDRESSED IN ADAR

Table 2: Summary of changes to PICO criteria since previous consideration by MSAC

☐ The proposed ADAR **will not** contain any changes to the PICO previously considered by MSAC.

☐ The proposed ADAR will reflect changes to the PICO as detailed below.

	PICO COMPONENT	COMPONENT DESCRIPTION AS CONSIDERED BY MSAC	REVISED COMPONENT DESCRIPTION AND RATIONALE
Instructional and sample text – please delete from completed template	Identify the relevant section of the PICO that has changed compared to the PICO considered by MSAC.	Copy the description from the Summary of the PICO criteria that was presented in the previous ADAR and considered by MSAC.	State what the change is and the rationale for the change. Where the rationale for the change is related to a matter that MSAC raised, cite the relevant paragraph of the MSAC PSD (use abbreviated referencing in tables). Where a component remains unchanged, insert 'No change' into this column.
	Population	Patients with Class II and Class III obesity with comorbidities, who have failed first-line treatments.	Patients with Class III obesity with comorbidities, who have failed first-line treatments. More evidence (quality and quantity) is available to support the clinical claims and economic analysis for patients with Class III obesity.
	PICO COMPONENT	**COMPONENT DESCRIPTION AS CONSIDERED BY MSAC**	**REVISED COMPONENT DESCRIPTION AND RATIONALE**
	POPULATION		

PICO COMPONENT	COMPONENT DESCRIPTION AS CONSIDERED BY MSAC	REVISED COMPONENT DESCRIPTION AND RATIONALE
<PRIOR TEST> (IF APPLICABLE)		
INTERVENTION		
COMPARATOR		
OUTCOMES **Safety**: **Effectiveness**: **Health care system outcomes**:		

PICO COMPONENT	COMPONENT DESCRIPTION AS CONSIDERED BY MSAC	REVISED COMPONENT DESCRIPTION AND RATIONALE
SYSTEMATIC REVIEW QUESTIONS – ORIGINAL AS CONSIDERED BY MSAC What is the safety, effectiveness, and cost effectiveness of [*XXXX] compared to [*XXXX] in [*XXXX]		**SYSTEMATIC REVIEW QUESTIONS – CHANGES** What is the safety, effectiveness, and cost effectiveness of [*XXXX] compared to [*XXXX] in [*XXXX]

DECLARATION

You:

a) warrant that You have read and understood the Guidelines for preparing assessments for the Medical Services Advisory Committee;
b) warrant that the proposed or amended medical service is able to be regarded as being a 'professional service' as defined by the *Health Insurance Act 1973* (Cth) if Your reapplication relates to a proposed medical service or an amendment to an existing medical service on the Medicare Benefits Schedule (MBS);
c) must ensure that Your reapplication does not include any personal information, as defined in the *Privacy Act 1988* (Cth), other than the name and contact details of any nominated expert(s) for Your reapplication for which You have obtained consent to provide;
d) acknowledge and agree that, if any other personal information is included in attachments in support of Your reapplication, the personal information must be provided with the consent of the individual to whom it relates (and evidence of consent must be provided to the Department of Health and Aged Care (Department) upon request;
e) warrant that You have obtained all required consents for the submission of information (including copyright) submitted in the reapplication, including having obtained any licences that may be required to allow the Department and the Medical Services Advisory Committee (MSAC) to use, reproduce, adapt and publish, for the purposes of the reapplication process and for related purposes, any third party material incorporated in the reapplication;
f) declare that, to the best of Your knowledge and belief after making all reasonable enquiries:
    i. the information contained in Your reapplication is true and accurate; and
    ii. no other information that is relevant to the funding of the medical technologies and services is known to either You or Your Organisation.
    'Information that is relevant' is that which may contradict or bring into doubt information given in the reapplication or otherwise influence the consideration by MSAC;
g) acknowledge that giving false or misleading information is a serious offence. You have not provided information that is false or misleading or omitted any matter or thing without which the information is misleading;
h) warrant that, if your reapplication relates to an investigative health technology, it reflects the perspectives of each requestor of the medical service/technology, the provider of the medical service/technology and, if necessary, the manufacturer of any device components;
i) warrant that, if your reapplication relates to an MBS listing, You have obtained a 'Statement of Clinical Relevance' from the most relevant professional medical college/society, in which they succinctly state their 'in-principle' support for the proposed medical service/technology;
j) acknowledge and agree that, if a reapplication is considered suitable for MSAC's consideration, the department will provide a redacted version of the reapplication to professional bodies/organisations and consumer organisations that have been identified in this or your previous application. It will also be provided to any additional groups or individuals that the Department deems appropriate/relevant for consultation and published on MSAC's website;
k) acknowledge and agree that, if You request to withdraw Your reapplication and MSAC has completed its consideration of the reapplication:
    i. the outcomes, recommendations, and/or advice of MSAC may be withheld or published by the Department, in whole or in part; and
    ii. MSAC's advice about the reapplication may still be provided to the Australian Government;
l) acknowledge and agree that all therapeutic goods used in the provision of medical services/in conjunction with the health technology will be, where applicable, separately assessed by the Therapeutic Goods Administration for inclusion on the Australian Register of Therapeutic Goods;
m) if a reapplication is made before the relevant therapeutic good(s) is or are included on the Australian Register of Therapeutic Goods:

i. warrant that You have evidence that the relevant sponsor/manufacturer has commenced the Therapeutic Goods Administration process; and

ii. agree that You will provide confirmation of inclusion of the product on the Australian Register of Therapeutic Goods before MSAC can finalise its recommendation in respect of the medical service/technology;

n) acknowledge and agree that information contained in a codependent listing submission/reapplication to one Committee may be used by the other relevant Committee(s) for the purpose of assessing the codependent submission/reapplication (for example: PBAC/MSAC, MDHTAC/MSAC etc.);

o) acknowledge and agree that if the reapplication is for a potential Highly Specialised Therapy (as defined under the National Health Reform Agreement Addendum 2020-2025) that is considered suitable for MSAC's consideration then the complete unredacted reapplication will be shared with representatives of State and Territory health agencies;

p) acknowledge and agree that:

i. You and/or Your Organisation are responsible for any reapplications made to the Health Products Portal by You;

ii. the Commonwealth of Australia is not liable or legally responsible for any reapplication made using Your Profile; and

iii. Your Organisation retains ownership of the reapplication and its contents, subject to the rights granted to the Department and others under the Terms of Use; and

p) warrant that You are authorised by Your Organisation to submit the reapplication.

☐ **I make the above declaration and agree to the Terms of Use.**

☐ **I consent to the collection, use and disclosure of personal information as set out in the Health Products Portal privacy collection notice.**

Signature:	
Name:	
Position:	
Company/Organisation:	