Medical Services Advisory Committee (MSAC) Reform Implementation

Process Framework

Version 1.0 March 2016

Contents

Glossary of terms and acronyms

Term	Definition
AHMAC	Australian Health Ministers' Advisory Council. Further information can be found at: http://www.coaghealthcouncil.gov.au/AHMAC/Introduction.
Application Manager	Stakeholders' central point of contact throughout the MSAC process.
APR	Application Progression Record. A central, integrated summary of the application's segmentation outcome, pathway and progression (as a historical reference) through the MSAC process. It embeds decision-making and is an acknowledged agreement between the Department and Applicant. Refer to **Section 3.2.1** for further information.
Citizen Space	Software program that acts as a platform for government consultation and stakeholder engagement.
Class III medical device or Class Active Implantable Medical Device (AIMD)	Classifications assigned by the Therapeutic Goods Administration (TGA) to characterise a medical device as 'high risk' against their medical devices regulatory framework. Further information can be found at: https://www.tga.gov.au/publication/australian-regulatory-guidelines-medical-devices-argmd.
Clinical novelty	Clinical novelty is the extent to which an application is proposing a 'new' service or change in an existing service. It is not just about the extent to which a service is innovative in terms of being 'new' per se but also whether an existing service is proposed to be applied in a significantly new way compared to how it is currently applied. Measuring clinical novelty allows an assessment of applications proposing small changes to potentially have a more expedited path through the PASC stages of the process .
Clinical trials	Clinical trials are conducted in a series of steps, called phases - each phase is designed to answer a separate research question: • Phase I is where researchers test a new treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range (if a drug), and identify side effects. • Phase II is where the treatment is given to a larger group of people to see if it is effective and to further evaluate its safety. • Phase III is where the treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the treatment to be used safely.

Term	Definition
Co-dependent service	Co-dependent Medicare Benefits Schedule (MBS) items involve an interaction or link of MSAC / MBS to the: • Pharmaceutical Benefits Advisory Committee (PBAC) / Pharmaceutical Benefits Scheme (PBS). • Prostheses Listing Advisory Committee (PLAC) / (Prostheses List). An application is considered co-dependent where the listings and their use needs to be combined (either sequentially or simultaneously) to achieve or enhance the intended clinical effect of either technology. For example, a drug/test combination where a new medicine seeking listing on the PBS may have a related pathology test that helps to determine the population group for that medicine.
Complexity	The complexity of an application is related to how many populations/clinical scenarios are to be targeted in terms of the use of the proposed service under consideration. This will inform whether one or two considerations by PASC may be required.
Consultative / Consultation service	Concept of a professional attendance defined in the *Health Insurance Act 1973* as an 'attendance by a [health] practitioner during which the practitioner: evaluates the patient's health-related issue or issues; formulates a management plan in relation to one or more health-related issues for the patient; provides advice to the patient and/or relatives (if authorised by the patient); provides appropriate health care; and records the clinical detail of the service(s) provided to the patient'. The type of evidence required and the way in which the evidence is assessed and presented will vary according to the nature of the consultative service, of which there are two broad categories - *specific* items and *global* items. A specific item is an attendance that covers a single clinical encounter.
CCA	Cost-consequences analysis . A form of economic evaluation in which the outcomes (of which a variety of measures are normally presented) are reported separately from costs.
CEA	Cost-effectiveness analysis . A form of economic analysis that compares the relative costs and outcomes (effects) of two or more courses of action.
CMA	Cost-minimisation analysis. Compares the cost per course of treatment when alternative therapies have demonstrably equivalent clinical effectiveness, and then it is only necessary to collect data about costs.
CUA	Cost-utility analysis. A form of financial analysis that estimates the ratio between the cost of a health-related intervention and the benefit it produces in terms of the number of years lived in full health by the beneficiaries.

Term	Definition
Epidemiology	Science that studies the patterns, causes, and effects of health and disease conditions in defined populations.
ESC	Evaluation Sub-Committee. Refer to **Section 3.1** for further information.
Global Consultation service	An attendance that covers multiple clinical encounters.
HTA	Health Technology Assessment. A range of processes and mechanisms that use scientific evidence to assess the quality, safety, efficacy, effectiveness and cost effectiveness of health services. HTA is commonly applied to pharmaceuticals (including vaccines), diagnostic tests, medical devices, surgically implanted prostheses, medical procedures and public health interventions. Further information can be found at: http://www.health.gov.au/internet/hta/publishing.nsf/Content/home-1.
Incremental cost/benefit	Comparative analysis of alternative courses of action in terms of the incremental cost and benefit of adopting one course of action over another.
Investigative service	Generates clinically relevant information about the individual to whom the service is rendered. To achieve an improvement in health outcomes, the investigative information must result in a change in the management of an intermediate therapeutic service. In this sense, it can only *indirectly* improve health outcomes and any improvement also needs to be balanced against any harm that the service might cause. For some investigative services, because of their purpose, direct evidence on health outcomes is mandatory (such as screening tests) but for most investigative services, a linked evidence approach is feasible using a HTA paradigm.
Linked evidence approach	For non-therapeutic service applications in which no direct evidence on health outcomes exists. For example, for investigative services it is possible to link evidence of service accuracy and the evidence supporting the therapeutic service that is subsequently delivered if both sets of evidence have been generated in similar patient populations and it is clinically sensible to link the two datasets.
MBD	Medical Benefits Division.
MBD MC	Medical Benefits Division Management Committee.
MBS	Medicare Benefits Schedule.
Mechanism (pathway element)	Mechanism refers to who will be primarily organising, developing and preparing the key documentation for consideration by MSAC for which there is two types; '*submission based*' where the applicant primarily performs this task or '*contracted*' where an independent assessment group contracted by the Department performs this task.

Term	Definition
Meta-analysis	Comprises statistical methods for contrasting and combining results from different studies in the hope of identifying patterns among study results, sources of disagreement among those results, or other interesting relationships that may come to light in the context of multiple studies.
MIRTL	MSAC Interim Reporting and Tracking Log. An MSAC interim reporting system.
MSAC	Medical Services Advisory Committee. Refer to **Section 3.1** for further information.
MSAC Exec	Medical Services Advisory Committee Executive Committee. Refer to **Section 3.1** for further information.
Narrative review	Tend to be mainly descriptive, do not involve a systematic search of the literature, and thereby often focuses on a subset of studies in an area chosen based on availability or author selection.
On-hold application	An applicant may request that their application be put 'on-hold', which can occur at any point during the MSAC process. The request may arise for a number of reasons which could include: they do not have enough time to satisfactorily consider the PICO Confirmation in time for a PASC meeting; the Applicant may wish to simply put their application on hold due to other commitments; the critique on their Assessment Report to ESC outlining that their evidence is weak or the economic assessment may not be complete etc. Placing an application on hold allows the applicant to reassess the evidence without having to withdraw from the process (and essentially starting over) or having their evidence considered by MSAC and having an unfavourable outcome. The Department can also put an application 'on-hold'.
PASC	PICO Advisory Sub-Committee. Refer to **Section 3.1** for further information.
PASC Intensity	The extent to which an application has to go through the PASC stage of the of the MSAC process; primarily the level of consideration likely to be required by PASC for an individual applications.
Pattern recognition	Identification of similarities across a group of applications to decide common process pathways through MSAC for applications sharing similar characteristics.
PICO Confirmation	Involves a clear articulation of the following aspects of the assessment: • Patients/Population – specification of the characteristics of the patients in whom the intervention is to be considered for use. • Intervention – specification of the proposed intervention and how it is delivered. • Comparator – specification of the therapy most likely to be replaced by

Term	Definition
	the proposed intervention. • Outcomes – specification of the health outcomes and the healthcare resources likely to be affected by the introduction of the proposed intervention.
Randomised controlled trial	A study in which members are randomly allocated either to a group that is exposed to a study factor of interest (drug/procedure) or an alternate group in which they are not exposed to the study factor or interest. To achieve comparable groups, subjects are allocated without the subject's or researcher's own influences driving the choice of group. The study population is then followed up overtime to see if differences occur in health outcomes across the two allocated groups and aims to infer whether or not there are any (causal) association between the study factor and outcome of interest.
Real life observational data	Observational data generated from a real life clinical setting where researchers observe patients and measure clinical factors of interest without having control over how those factors (including treatment) are assigned to patients. This is opposed to a controlled setting in which experimental data is generated where researchers intentionally alter one or more clinical factors (including how treatment is assigned) in order to study the effect of doing so.
Segmentation	Process of categorising characteristics of an application to inform how to manage an application at each stage of the MSAC process.
Stakeholder	Includes consumers, patients and/or relevant public.
Suitability	An assessment of suitability of an application refers to whether an application is suitable to commence the MSAC process from the outset (is it appropriate for the application to be considered by MSAC) and whether it is necessary or feasible to conduct a health technology assessment to inform a government decision about the proposal for funding contained in the application.
Therapeutic service	Improves health outcomes *directly*, no other intermediate medical service needs to be provided to achieve the improvement in health outcomes.
Time horizon	A fixed point of time in the future at which point certain processes will be evaluated or assumed to end. Also known as a planning horizon.
Triage	Generic term describing the front end of the MSAC process from receipt of application through to the end of an assessment of an application's suitability.

1 Introduction

1.1 Background - MSAC and reform

The Medical Services Advisory Committee (MSAC), established in 1998, is an independent scientific committee comprised of individuals with expertise in clinical medicine, health economics and consumer matters. It is supported by two sub-committees, the Evaluation Sub-Committee (ESC) and the PICO Advisory Sub-Committee (PASC) (formally the Protocol Advisory Sub-Committee).

MSAC was established to strengthen the sustainability of the health system, and its mission is to provide independent and expert advice to the Minister for Health (Minister) on the evidence relating to the relative safety, clinical effectiveness, cost-effectiveness and total cost (and other relevant information) of proposed medical technologies and procedures. This advice informs Australian Government decisions about public funding for medical services, with the overall aim of improving health outcomes for the Australian community as well as representing value-for-money for the Australian healthcare system.

MSAC's advice usually relates to new services to be funded under the Medicare Benefits Schedule (MBS). However its role has grown to include all proposed changes to the MBS, co-dependant technologies and applications for funding outside the MBS (such as blood products, referrals from the Australian Health Ministers' Advisory Council (AHMAC) and at the direction of the Minister).

The key benefits of using MSAC to provide advice to the Minister on whether or not to publicly fund medical services are:

- It is a transparent process that provides an evidence-base for government consideration of public funding.
- The process provides balance across the competing objectives of optimising safety and clinical effectiveness whilst ensuring MBS expenditure remains sustainable.
- The functions and composition of the committees provide a level of expertise which is not otherwise available within the Department.

Since its inception, MSAC has been subject to a number of reviews, reforms and budget measures, these being:

- HTA Review (2009)[1].
- Quality Framework (to 2011)[2].
- Comprehensive Management Framework (to 2013)[3].
- Ongoing initiatives such as ongoing revision of templates when feedback is received.

[1] http://www.health.gov.au/internet/main/publishing.nsf/Content/AF68234CE9EB8A78CA257BF00018CBEB/$File/hta-review-report.pdf.

[2] http://www.health.gov.au/internet/main/publishing.nsf/Content/MBS_Quality_Framework.

[3] This was a Commonwealth Budget measure that built on the Quality Framework. Information is available here: http://www.health.gov.au/internet/main/publishing.nsf/Content/New_MBS_Items.

Key to these reforms was the need to support the policy objectives of the MBS. That is, ensuring access to cost-effective health services (including through MBS subsidies for clinically relevant services) whilst supporting the sustainability of MBS in the face of rising costs and demands for medical services, especially complex technologies and devices. Reforms have particularly focused on the efficiency, transparency, accountability and consistency of processes, including improved coordination and streamlining for applicants.

In June 2014, the Department of Health (the Department) engaged the Apis Group (Apis) to help focus, strengthen and accelerate the reform agenda, particularly to review the current MSAC processes and provide advice on how these processes could be improved, based on stakeholder discussions. In October 2014, Apis provided the Department with a final report that identified the potential for significant improvement in four key areas, with eight recommendations. These recommendations were accepted by departmental executives on 24 October 2014. Following this, in December 2014 the MSAC Reform Team was established (comprising departmental and Apis staff) to implement the agreed recommendations within the report.

Some of the key messages the Department has heard from stakeholders (including committee members, applicants, HTA groups and consumers/patients) through the current reforms include a desire for:

- The Department to affirm its responsibility for the process including re-establishing timeframes and deadlines for applicants noting that applications are made to the Department for public funding of medical services and the Department refers applications to MSAC for independent advice.
- Flexibility in the process to allow applications of differing complexity to be dealt with via pathways other than a full health technology assessment.
- Clear guidelines and advice for applicants on the MSAC process and what is expected of them, as well as what information they will be required to provide throughout the process.
- A more transparent process where stakeholders are clear about the expected pathway, timeliness of consideration, internal processes and related timeframes, and the post-MSAC processes. Stakeholders have highlighted that they are more concerned about the efficiency of the process rather than expedience.
- Removal of repetition throughout the process so that relevant documents build on each other rather than regurgitating the same information each time.
- A single Departmental contact or area for all stakeholders associated with an application to ensure consistency of messaging.

1.2 Purpose of Framework

The two main overarching purposes of the Process Framework (Framework) are to: (a) enable the Department to triage applications, specifically to identify which applications are suitable for consideration by MSAC versus not; and (b) facilitate suitable applications through a robust, consistent and evidence-based process. Specifically, it will ensure the information provided to MSAC has sufficient rigour to enable MSAC to provide quality advice in a timely manner to the Minister, minimising the need for resubmission and reiteration of work through the committees.

This Framework provides:

- Process and pathway transparency which assists to ensure procedural fairness to all stakeholders, is defensible yet ensures flexibility.
- The potential to organise applications based on their readiness to progress through the MSAC process.
- Rigour and governance around the analysis of applications by setting parameters to guide and inform decision-making.
- Guidance and rationale on the types and level of information required through the MSAC process.
- Effective planning of the process, timeframes and effort, leading to increased efficiency through tailored effort.

1.3 Outputs of the Framework

This Framework is intended to complement the MSAC assessment processes by providing a robust and consistent approach to the management of applications.

Broadly, the Framework provides outcomes in two aspects:

a) Classifying or processing applications into general groups based on relevant decision factors for pathway intensity.

b) Identifying planning for MSAC and its sub-committees, and departmental workload and activities in relation to resource intensity and effort.

The Framework seeks to integrate the core purpose and principles of MSAC[4] into the end-to-end application management process. By conducting the process identified in the Framework for each application, the Department will:

- Be able to identify (to an extent, based on the provision of high-level information) if applications are suitable to progress through the MSAC process.
- Provide guidance to applicants on alternative options/pathways where MSAC may not be appropriate.
- Guide applicants through the appropriate MSAC pathway.
- Provide advice on the requirements of the level of complexity and timing of evaluation assessment.

[4] Terms of reference for MSAC, ESC and PASC are all available on the MSAC website www.msac.gov.au

- Identify the appropriate pathway mechanism (contracted or submission-based) for applications.
- Have a central, integrated record of the application's progression through the process documented in the APR.

In realising these objectives, the Framework delivers on:

- Transparency in decisions.
- Consistency in the process.
- Clear guidance for all stakeholders - internal and external.
- Effort requirement for processing applications that is commensurate with relevant criteria.

1.4 Requirement for Segmentation

One of the key recommendations of the October 2014 report (refer to **Section 2.1**) was the implementation of a Risk Management Framework, to provide the basis for understanding and classifying applications. That is, the need to apply commensurate rigour of assessment, depending on an application's risk and benefit.

Since implementation of the report's recommendations and discussions with relevant stakeholders, it is seen as appropriate to shift from a requirement of a 'Risk Management Framework' (i.e. outlining the relevant 'risks' of an application) to a 'Process Framework' (i.e. outlining standardised and robust criteria to group and inform the pathway and treatment of an application).

1.5 Alignment with MSAC

It is the intention of this Framework to facilitate the work of MSAC - which is to provide independent advice to the Minister, through the Department of Health, on the strength of the evidence in relation to the medical services it considers. Specifically, it is MSAC's role to look at the merits of each application in relation to comparative safety, effectiveness, cost effectiveness and total cost, using the best available evidence.

The Framework aims to identify:

- If the application is appropriate and feasible for MSAC consideration.
- Where there are likely to be, not only opportunities to expedite particular parts of the process, but also specific issues or complexities surrounding the application.
- Whether any components are going to require more scrutiny or intensity of effort, so that appropriate planning can occur.

1.6 Alignment with Government

This Framework and approach is developed in line with the principles of the *Public Governance, Performance and Accountability Act 2013* (PGPA Act), which governs the use and management of public resources. The PGPA Act aims to improve performance, accountability, risk management and service delivery across Government.

The efficient and effective use of public funds through listing on the MBS, other public funding programs (be it Commonwealth only funded programs or programs where there is joint funding and/or service delivery responsibility between the Commonwealth and other jurisdictions), committee resources and/or departmental resources, is a cornerstone of this Framework.

Following MSAC's consideration of an application for public funding, the Department of Health is required to consider the financial impact to Government, consult with relevant stakeholders, seek Cabinet agreement and draft and implement legislative change to amend or add an item to the MBS. There is no obligation on Government to accept or implement the advice MSAC provides.

1.7 Framework implementation

This Framework is intended to apply to all new and resubmitted applications that are to progress through the reformed MSAC process. However circumstances may arise with future applications which do not permit them to be neatly categorised against the Framework and the intent of the Framework is not for it to be a 'be all and end all' but rather identify common and recurring characteristics across applications which is then used to broadly inform how to best handle individual applications through the MSAC process in an efficient way.

The Department implemented this Framework on 10 June 2016.

1.8 Governance

Governance relates to the structures and mechanisms used to manage the segmentation process. Departmental staff in the Medical Financing and Listing Branch within Medical Benefits Division (MBD) of the Department are responsible for the end to end operation and management of the process; primarily application managers with support of Departmental medical advisers and oversight by senior executive of the Division (both First Assistant Secretary and Assistant Secretaries).

The other relevant governance committee to provide independent and expert advice in relation to the Segmentation process is the MSAC Executive Committee (MSAC Exec). This committee comprises the following attendees (or delegate):

- MBD First Assistant Secretary.
- Chair MSAC.
- Deputy Chair MSAC.
- Chair Evaluation Sub-Committee (ESC).
- Chair PICO Advisory Sub-Committee (PASC).
- Chief Medical Officer (or proxy).

1.9 Reviewing the Framework

This Framework and supporting documents are to be reviewed annually against the overarching MSAC processes. Stakeholders will be advised, via the MSAC Bulletin, if and when an updated version of the Framework is available.

1.10 Related documents

In line with the implementation of the Process Framework and MSAC reform activities, relevant MSAC documents will be updated or developed, including the Technical Guidelines, the MSAC Application Form and Application Form Guidelines, the APR, PICO Confirmation Template, Assessment Report Templates etc.

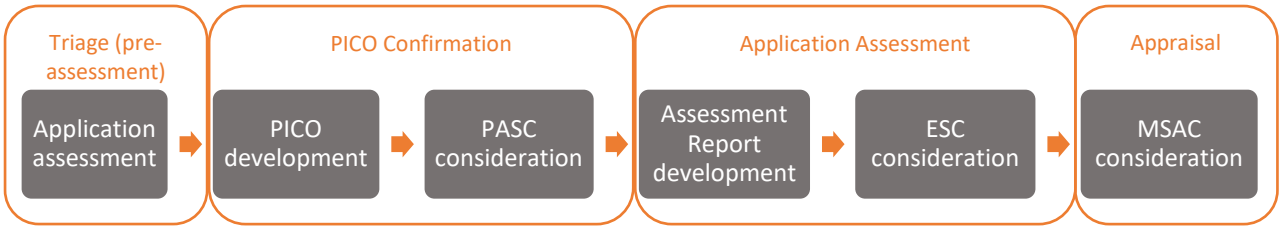
2 Segmentation through the MSAC stages

2.1 Summary of MSAC stages

The MSAC process includes four broad stages and is supported by one main committee (MSAC) and two sub-committees (PASC and ESC). The MSAC and its sub-committees are further supported by clinical experts and HTA groups. **Figure 1** below provides a high-level representation of the overall MSAC process, including the stages and committee/sub-committee involvement. Note, the passage of each application through this end-to-end MSAC process may be varied due to some applications not requiring a full assessment.

The information outlined in **Figure 1** and **Table 1** below is provided as an example based on current MSAC process and structure. The final process and structure in this Framework will be determined by the end-to-end operational review of MSAC.

Figure 1: High-level MSAC process



Information relating to each stage including the purpose and major stakeholder involvement is outlined below in **Table 1**.

Table 1: MSAC stages

Stage	Description
Triage (pre-assessment)	The purpose of this stage is to ensure the applicant is aware of the process, likely pathway and evidence expectations. This stage involves the Department verifying the **availability** of evidence for assessment, consideration of whether the application is suitable for consideration by MSAC and consideration of what would be the most efficient pathway through which the application will be progressed. Targeted public consultation on the completed application form will also be undertaken. The major stakeholders in this stage are the applicant, application manager, policy officer(s), PASC Secretariat, and relevant medical profession.
PICO Confirmation	The purpose of this stage is to develop the PICO Confirmation and determine the relevant clinical algorithms to progress an assessment. At the end of this stage, the applicant, Department and PASC aim to have an agreed PICO to undertake a systematic review of the evidence and generate an economic evaluation/model. The Department will engage a HTA group to develop the PICO Confirmation which will clearly articulate the following aspects of the assessment: • Patients/Population – specification of the characteristics of the patients for whom the intervention is to be considered for use. • Intervention – specification of the proposed intervention and how it is delivered. • Comparator – specification of the service (if there is a service)/usual standard of care most likely to be rendered in the population under consideration in the absence of the proposed intervention being available in the Australian health care system. • Outcomes – specification of the health outcomes and the healthcare resources likely to be affected by the introduction of the proposed intervention. It also informs the development of a decision analytic framework that will underpin the economic evaluation within the assessment report in the application assessment phase. The final PICO confirmation will be made available on the MSAC website and Citizen Space for public consultation at any time in the MSAC process. This provides an opportunity for all interested parties to comment on the proposed assessment approach. The major stakeholders in this stage are PASC, PASC Secretariat, applicant, application manager, policy officer(s), clinical expert(s), MSAC Exec, HTA groups and consumers/patients.
Application assessment	The purpose of this stage is to review the Assessment Report to identify the gaps and levels of uncertainty in the evidence, in formulating advice on public funding. The APR will outline whether the application will proceed down a contracted or submission based assessment pathway. The APR will be available on the MSAC website for public consultation at any time in the application's MSAC process. The purpose of ESC is to provide advice on the quality, validity and relevance of internal and external assessments for applications being considered by MSAC. The major stakeholders in this stage are ESC, ESC Secretariat, clinical expert(s), application manager, policy officer(s), MSAC Executive, HTA groups and consumers/patients.

Stage	Description
Appraisal	MSAC considers a wide range of information, including the assessment report assessing the evidence; the independent critique of the report, feedback from the applicant, the ESC Report on the evidence; any feedback on the ESC Report provided by the applicant and/or other relevant parties; and the individual expertise of MSAC members. MSAC's advice to the Minister is made public in the form of by a Public Summary Document (PSD) that explains the rationale for MSAC's advice and is made available on the MSAC website. Refer to **Section 2.1** for the purpose of MSAC. The major stakeholders in this stage are MSAC, MSAC Secretariat, application manager, policy officer(s), and MSAC Exec.

2.2 Segmentation

Segmentation occurs throughout the application's lifespan. The APR is the tool used to operationalise segmentation.

2.2.1 Application Progression Record

Each application is given an APR. The APR will summarise the outcome of segmentation, document the pathway of an application (eg standard/comprehensive/expedited PASC or contracted/submission based assessment) and document the predicted milestones of the applications (eg expected meeting dates of PASC, ESC, MSAC).

There are three times in an application's MSAC process that segmentation will occur:

- **APR Creation** – occurring at the commencement of the Triage (pre-assessment) stage. This is the first time the segmentation process occurs and is pivotal in determining both the suitability of the application and informing the pathway process and intensity from the beginning of the MSAC process. This stage also enables the analysis of the likely resources required, and the level of effort needed to progress an application as well as identifying obvious gaps in information within the application, and encouraging applicants to address components at an earlier stage (see F**igure 3**).
- **APR check-point** – occurring at the completion of the PICO Confirmation stage. This enables potential reassessment of the segmentation criteria based on additional information and ensures systematic monitoring, focusing on the quality of applications. This check-point is an important process to validate and assess whether the updated segmentation has deviated (and if so, how much) from the initial assessment (see **Figure 4**).
- **APR evaluation** - occurring at the completion of the appraisal stage. This enables evaluation of the final segmentation criteria and pathway against the initial assessment and to see the extent of any variation. This becomes a crucial evaluation tool to inform future refinements and continuous improvement of the overall segmentation process (see **Figure 5**).

Figure 2 on the following page outlines the incorporation of segmentation within each MSAC stage, including the segmentation inputs and outputs of each stage and the relevant information flows. Further to this, **Figures 10** and **11** provide more detail about the decision making process that the Department will follow in consultation with the applicant.

Figure 2: Overview of Segmentation through the MSAC stages

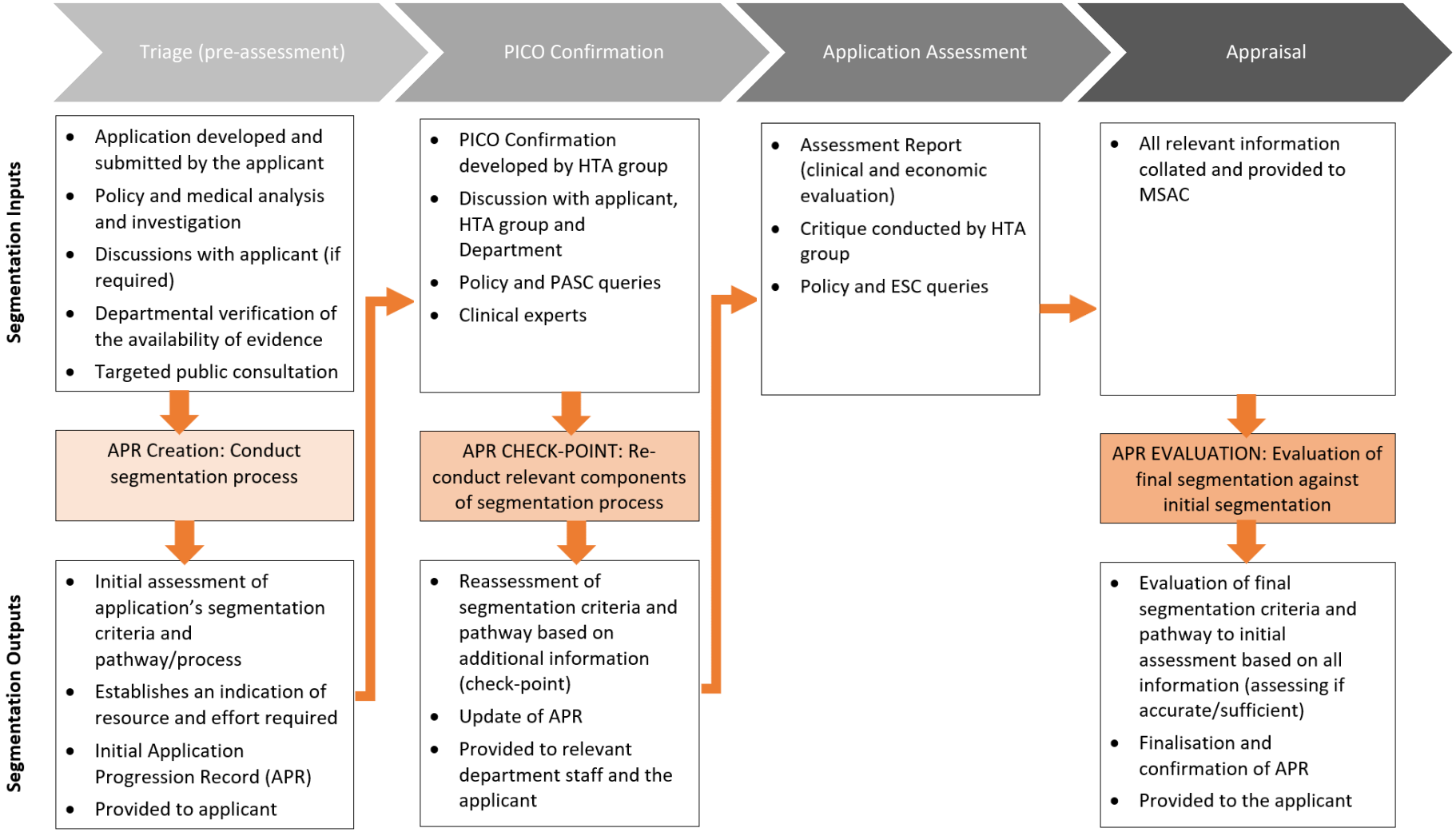


Figure 3: APR Creation

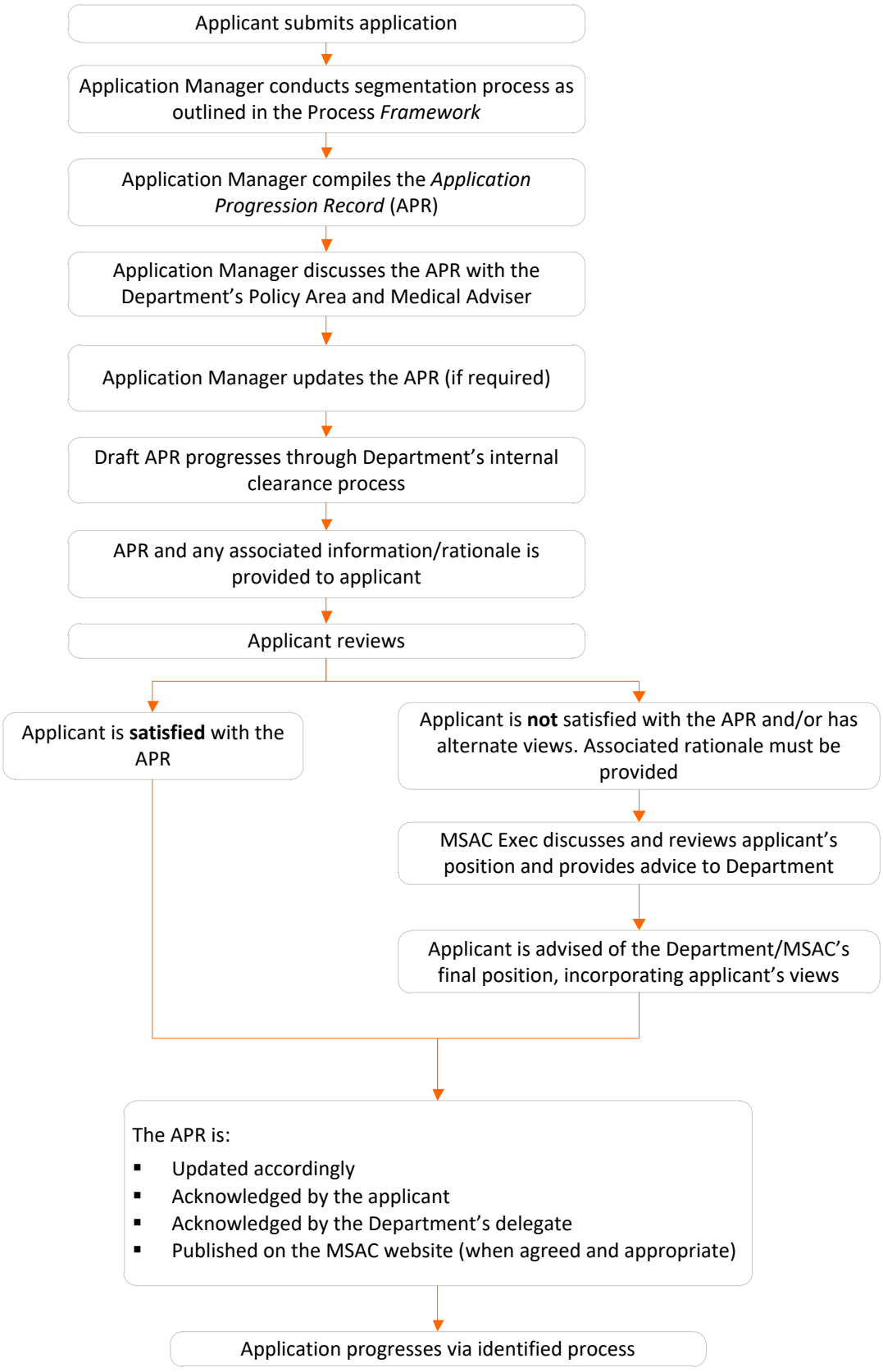


Figure 4: APR check-point

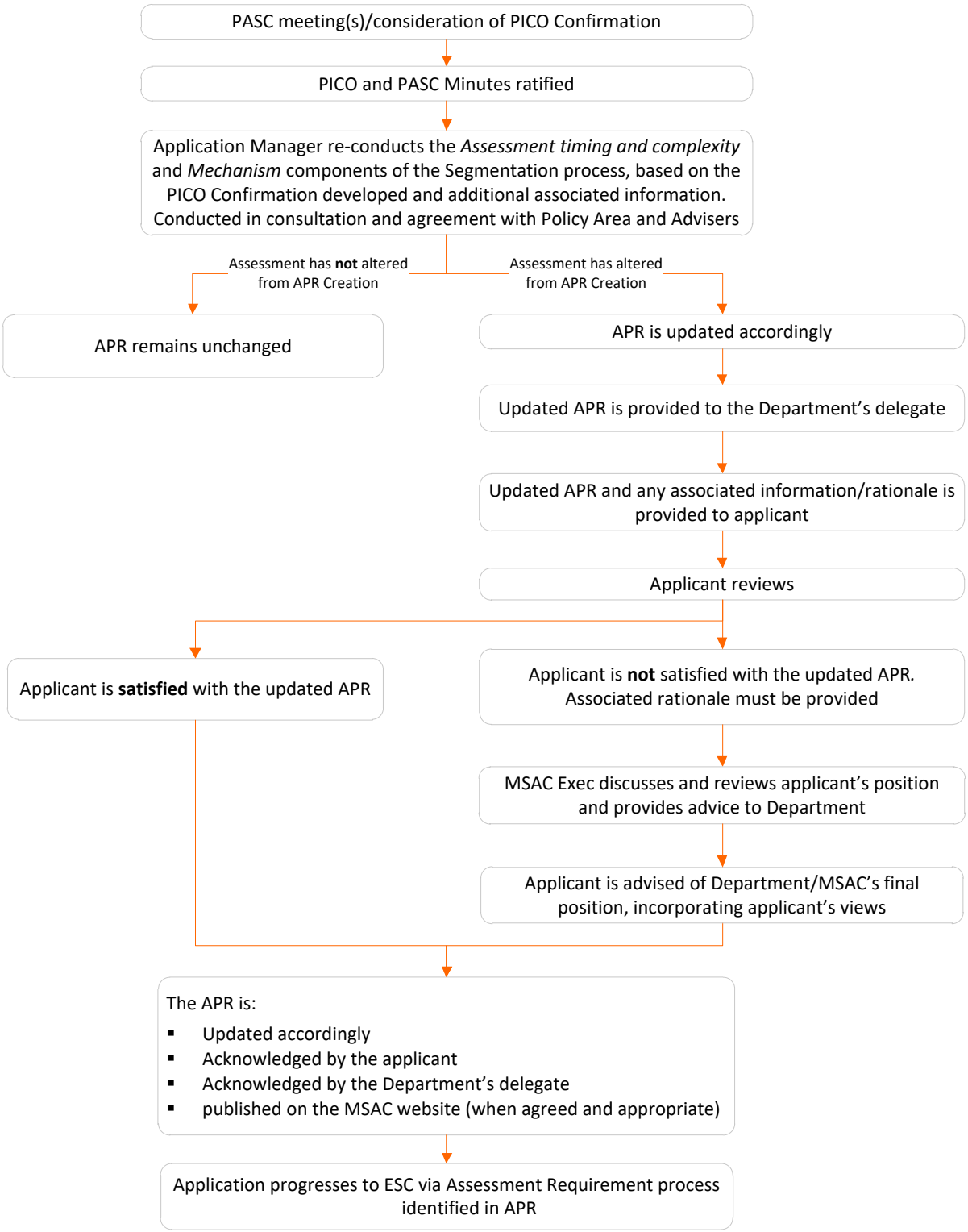
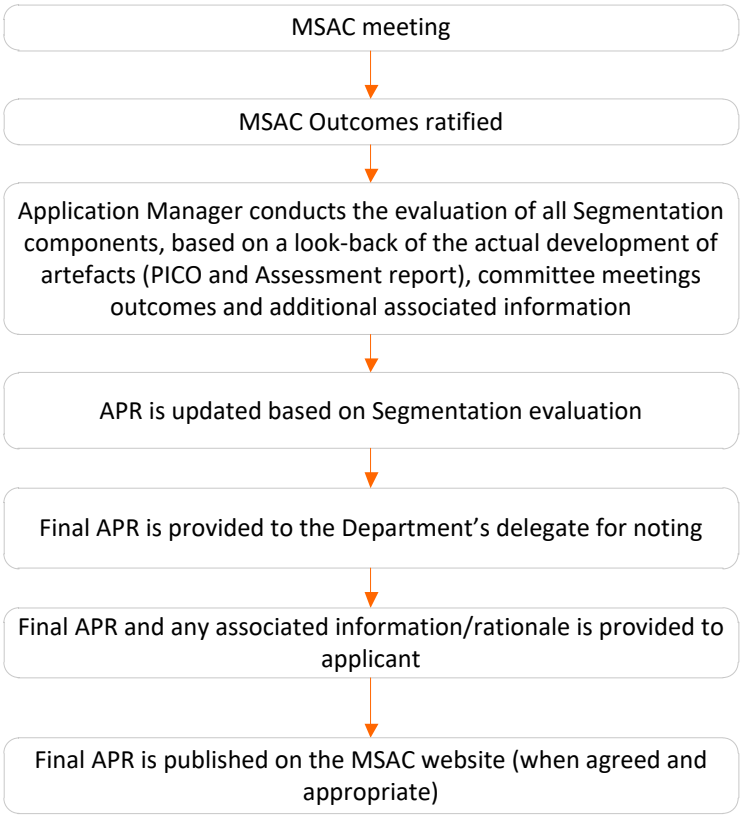


Figure 5: APR evaluation



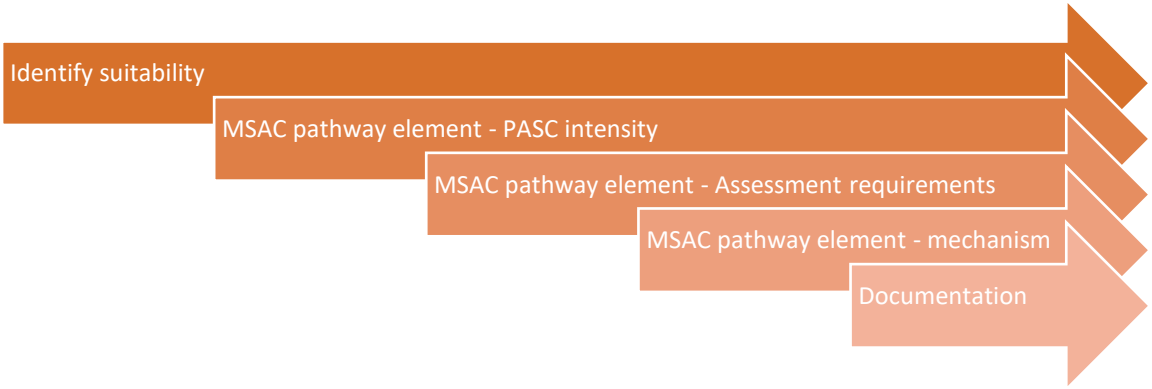
3 Segmentation objectives

Segmentation has five main objectives, outlined in **Figure 6** below.

Apart from the 'suitability' component, which must be conducted first, all other components can be conducted in parallel with each other.

Refer to **Section 3** (segmentation through the MSAC Stages) for information regarding how to conduct the segmentation process at each MSAC stage – for the purposes of APR creation, APR check-point and APR evaluation.

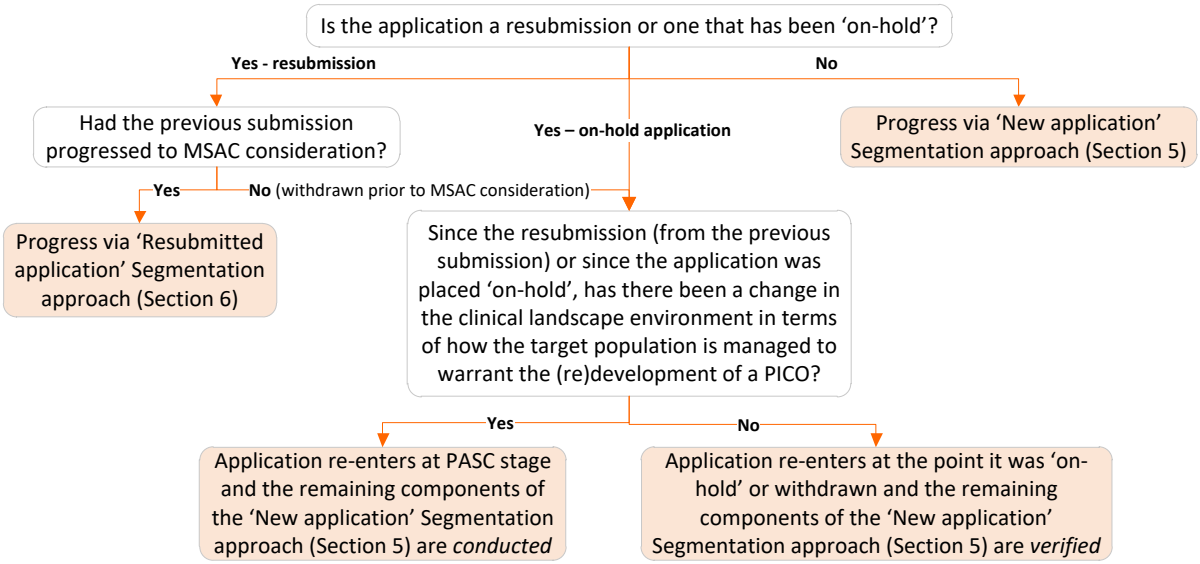
Figure 6: Segmentation Objectives



3.1 New application or resubmitted application?

Whether an application is to progress as a 'new application' or a 'resubmitted application' is outlined below in **Figure 7** and detailed in **Sections 5** and **6** respectively. This consideration also includes applications considered 'on-hold'.

Figure 7: New application or Resubmitted decision criteria



4 Segmentation objectives – new applications

Based on **Figure 6** (segmentation objectives), this section outlines the specific segmentation for new applications as shown in **Figures 8** and **9** which provides a visual representation of the key elements of the Framework and the decision criteria flowchart for new applications, respectively.

Figure 8: Key elements – New applications

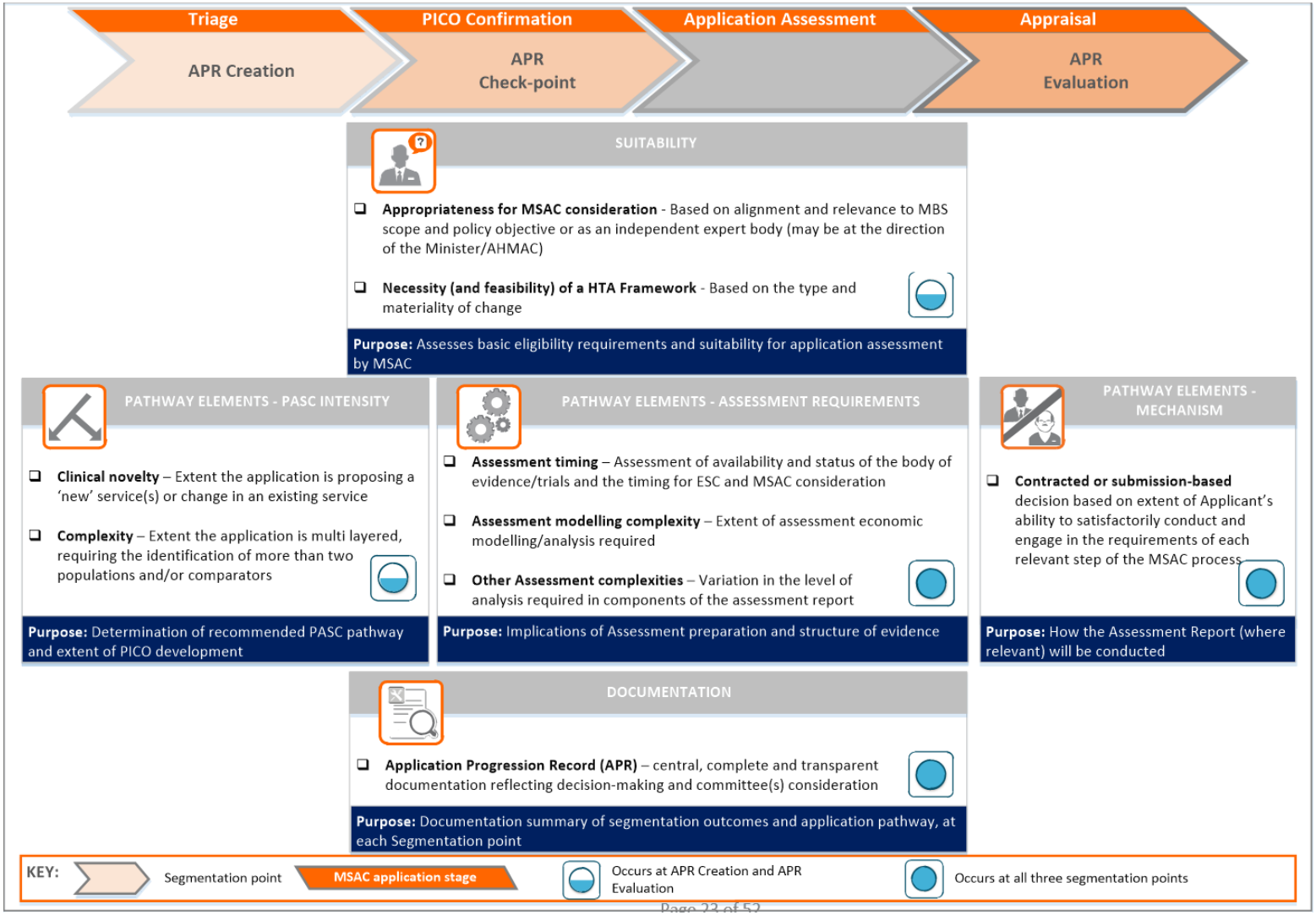
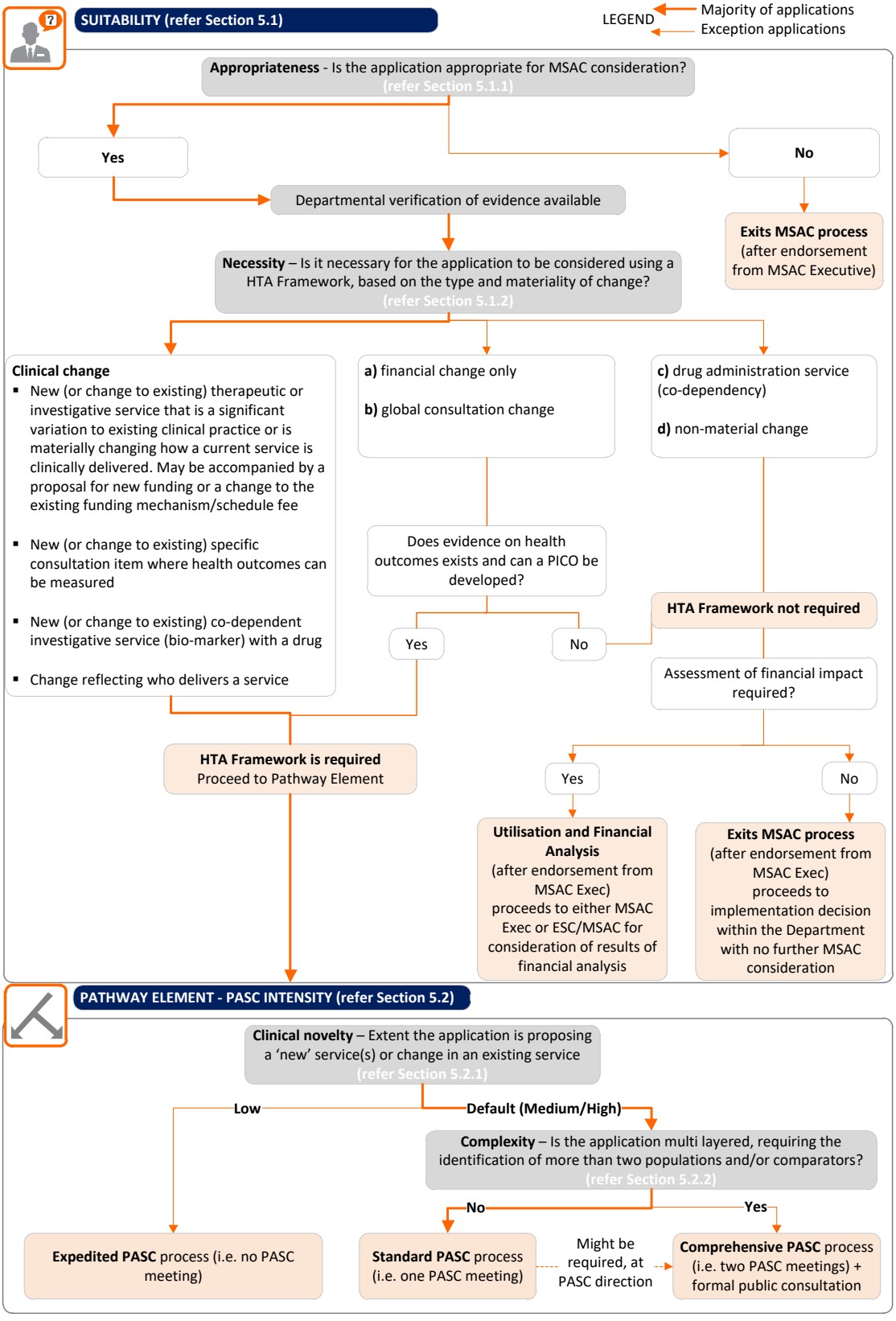


Figure 9: Decision criteria flowchart – New applications



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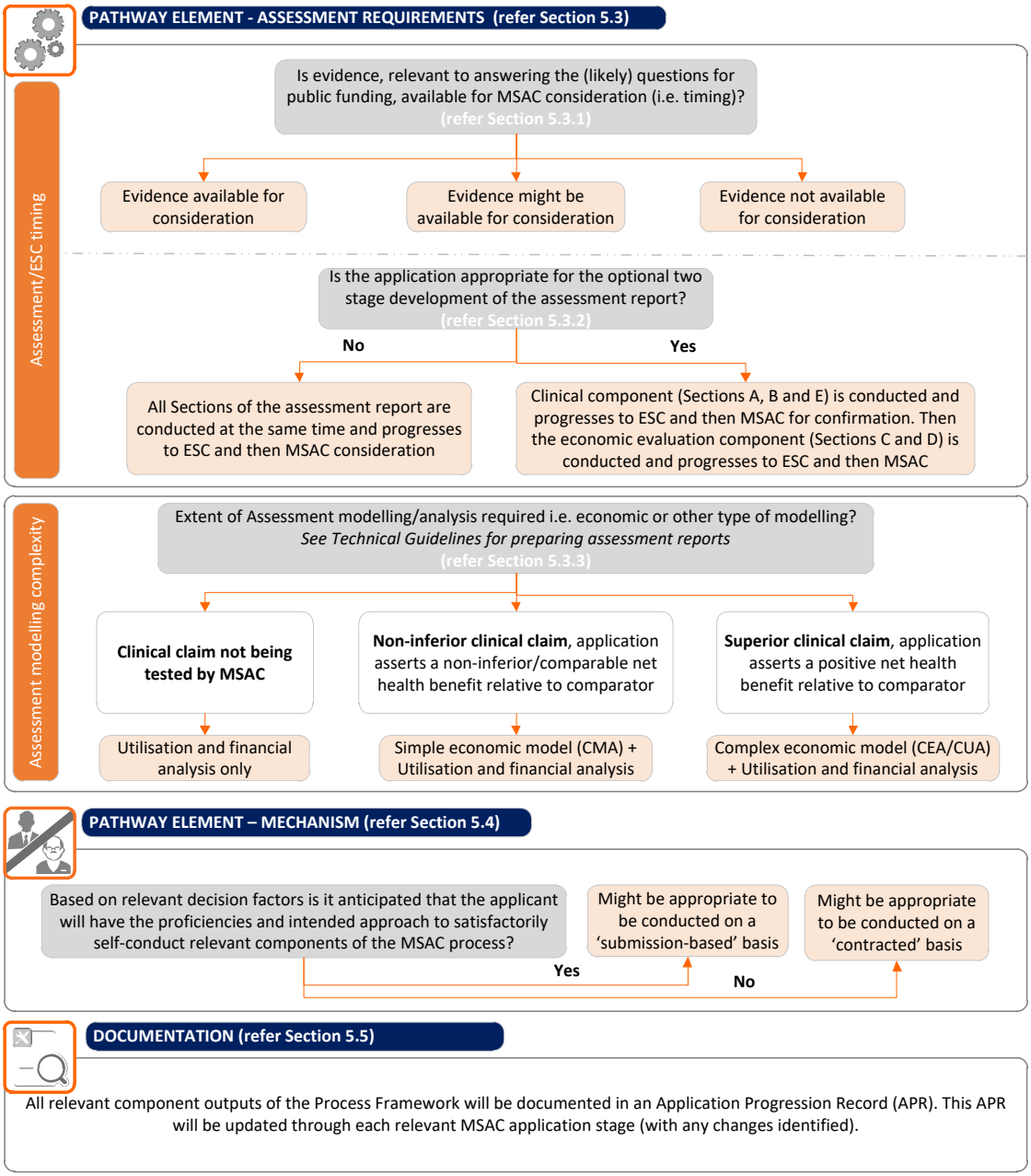

PATHWAY ELEMENT - ASSESSMENT REQUIREMENTS (refer Section 5.3)
Assessment/ESC timing
Is evidence, relevant to answering the (likely) questions for public funding, available for MSAC consideration (i.e. timing)? (refer Section 5.3.1)
Evidence available for consideration
Evidence might be available for consideration
Evidence not available for consideration
Is the application appropriate for the optional two stage development of the assessment report? (refer Section 5.3.2)
No
Yes
All Sections of the assessment report are conducted at the same time and progresses to ESC and then MSAC consideration
Clinical component (Sections A, B and E) is conducted and progresses to ESC and then MSAC for confirmation. Then the economic evaluation component (Sections C and D) is conducted and progresses to ESC and then MSAC
Assessment modelling complexity
Extent of Assessment modelling/analysis required i.e. economic or other type of modelling? See Technical Guidelines for preparing assessment reports (refer Section 5.3.3)
Clinical claim not being tested by MSAC
Non-inferior clinical claim, application asserts a non-inferior/comparable net health benefit relative to comparator
Superior clinical claim, application asserts a positive net health benefit relative to comparator
Utilisation and financial analysis only
Simple economic model (CMA) + Utilisation and financial analysis
Complex economic model (CEA/CUA) + Utilisation and financial analysis
PATHWAY ELEMENT – MECHANISM (refer Section 5.4)
Based on relevant decision factors is it anticipated that the applicant will have the proficiencies and intended approach to satisfactorily self-conduct relevant components of the MSAC process?
Might be appropriate to be conducted on a 'submission-based' basis
Might be appropriate to be conducted on a 'contracted' basis
Yes
No
DOCUMENTATION (refer Section 5.5)
All relevant component outputs of the Process Framework will be documented in an Application Progression Record (APR). This APR will be updated through each relevant MSAC application stage (with any changes identified).

4.1 Suitability

The first objective of segmentation is to assess the basic eligibility requirements and suitability for application assessment by MSAC. The suitability assessment considers two broad components – the appropriateness of consideration by MSAC, and the necessity and feasibility for the application to be assessed using a HTA Framework. Both are detailed below.

These fundamental elements are considered from the outset so as to not waste public, departmental and applicant resources on progressing unsuitable applications.

4.1.1 Appropriate for MSAC consideration?

This first component looks at whether or not the application is appropriate for MSAC consideration based on the MSAC's Terms of Reference[5], in particular:

- Where MSAC provides independent advice to the Minister on the safety, clinical effectiveness and cost effectiveness and total costs of medical services proposed for listing on the MBS, including those that involve new or emerging technologies and procedures and amendments to existing MBS items.

- In its capacity as an independent expert body on HTAs for public funding of new, emerging or amendments to non-MBS technologies and procedures (which may be at the direction of the Minister or AHMAC).

Given that the MSAC process is not cost recovered, the Department has responsibility for facilitating applications through the MSAC process with the use of taxpayers' money. Therefore the Department must make a decision as to whether commencing an application through the MSAC process is aligned with the principles of the *Public Governance, Performance and Accountability Act 2013* (PGPA Act). As outlined in the PGPA Act, it is a fundamental requirement of all Commonwealth entities to ensure the proper use and management of public resources, and in this instance, whether the progression of an application is an efficient, effective, economical and ethical use of tax payers' money. The following types of applications need to be flagged early to test whether it is appropriate for them to be considered by MSAC either because they potentially out of scope in terms of MSAC's remit (as stated in their Terms of Reference) or progressing them through the MSAC process may not be consistent with the principles of the PGPA Act.

Applications that are specifically seeking funding on the MBS that do not meet the definition of a professional service under *the Health Insurance Act 1973*. The *Health Insurance Act 1973* stipulates that Medicare benefits are payable for clinically relevant professional services. A professional service is clinically relevant *if it is generally accepted by the medical profession as necessary for the appropriate treatment of the patient*.

To assist in making a decision as to whether an application meets this definition of a professional service, it is a mandatory requirement for applicants seeking MBS funding to have a statement of clinical relevance from the relevant part of the medical profession; specifically whether the medical profession generally accepts the proposed service as a 'necessary' treatment (and not simply treatment that is regarded as convenient or desirable). It should be noted for emerging services that remain largely experimental, are primarily rendered for the purposes of research rather than direct clinical care and are not yet regarded a standard treatment for the patient group in question, they would most likely not meet the definition of

[5] Available at: http://www.msac.gov.au/internet/msac/publishing.nsf/Content/msac-tor-1.

a professional service. Ensuring it is a mandatory requirement for applicants to receive a statement of clinical relevance from the medical profession and relevant consumer organisations will not only provide valuable insights into the potential place of the proposed service in the clinical management of the patient group in question, it will also trigger general commentary from the medical profession as to where the evidence base underpinning the application is broadly at and whether it is too soon to commence an application to MSAC altogether (in addition to the issue of the timing of the assessment of evidence – see **Section 5.3.1**).

The applicant will also be responsible for providing a list of relevant evidence, intended as a snapshot, in the Application Form, that they plan to have considered, however, if the view of the medical profession is that there is a high probability from the outset that there is little, to no evidence to support the clinical claim of the applicant, or the applicant has presented their proposal far too early in the evidentiary cycle, then it would be not appropriate for the application to commence the MSAC process. This decision, however, can be revisited at a later date depending on how the evidence evolves overtime. This principle primarily applies for those applications where a clinical change is proposed (see **Section 5.1.2**). It should be emphasised that Applicants when filling out the Application Form are not expected to provide a detailed analysis of the body of evidence in question (in terms of results of trials and what the evidence is actually saying) as a detailed assessment of this evidence is conducted as part of the subsequent health technology assessment which is then followed by an independent appraisal by MSAC itself, not the Department. However if it is known ahead of time that there is likely to be no evidence to 'populate' a health technology assessment and to test the clinical claim outlined in the application, then a decision needs to be made as to whether this is an efficient and effective use of taxpayers money to commence the MSAC process to assess the application.

Applications with significant policy or implementation issues requiring a rapid strategic discussion within MBD (and where relevant, other Divisions of the the Department) to inform an assessment of whether or not it is appropriate for an application to proceed through the MSAC process. For example whether an alternative process within MBD (or more broadly across the Department and health care system) is a more appropriate way forward (instead of MSAC) to progress consideration of the proposal by Government, or, whether the policy and implementation issues identified are not deemed significant enough to stop an application, but rather, are regarded as issues that can be considered and addressed concurrently as the application progresses through the MSAC process.

Examples of such applications include those outlining proposals for services that are currently prohibited on the MBS under existing generic rules and regulations. This could either be because the specific medical service proposed is currently prohibited (for example a health screening service only attracts Medicare benefits when the Minister directs it to do so) or an application in addition to proposing a new/change to an existing service is also seeking to change generic rules and regulations relevant to the specific service. For example, applications seeking changes to MBS provider eligibility such as a group of medical or health professionals seeking changes to generic rules and regulations to enable them to change how they access the MBS such as a health professional group wanting to provide services 'on or behalf of' other health professional groups. Another example of an application that may not be appropriate for consideration by MSAC (unless the Minister or AHMAC otherwise directs MSAC to consider) are ones for highly specialised tertiary services that aim to manage either rare or highly complex conditions. In this example advice would need to be sought from across the Department as to whether the application is more appropriate to be considered by an alternate process i.e. is the proposal potentially more suited for inclusion on the Nationally

Funded Centre (NFC) Program which is assessed by the NFC Reference Group which then reports to AHMAC. While MSAC has previously considered proposals of this nature up to the mid 2000s, it has not considered NFC proposals recently.

Applications where the application form is simply not completed for the Department to formally progress to an assessment of appropriateness. In this instance, the applicant is informed that it is mandatory for the Application Form to be completed before it is allowed to progress any further to a formal assessment of suitability.

4.1.2 Necessity of a HTA Framework?

This second component of the suitability assessment seeks to categorise the type and materiality of the application to determine whether it is necessary for the application to be considered via a HTA Framework, including consideration of whether using a HTA Framework is an efficient and effective use of resources in assessing the merits of applications. There are two broad types – application consideration through a HTA pathway and alternate (non-HTA) pathways. These are both outlined on the following pages and referred earlier in **Figure 9**.

Application consideration through a HTA pathway

For this category of applications, the net clinical impact (in terms of definitive health outcomes) is able to be measured (directly or indirectly). This enables a comparative assessment of the clinical consequences of the application (in terms of safety and clinical effectiveness) to be conducted as well as a comparison of cost and clinical consequences (cost effectiveness) via a HTA Framework.

The relevant types of these applications are outlined below.

New (or change to existing) therapeutic or investigative service

These types of applications continue to constitute the majority of applications presented for MSAC consideration. If an application is proposing a material change to how a therapeutic or investigative service is clinically delivered (for example in terms of the technology/approach and who receives the service), then a comparative assessment via a HTA pathway is necessary.

An example of a therapeutic service may include a new surgical procedure and approach to treat particular medical conditions or to change an existing item to accommodate the use of a particular technology not currently covered under the item. An example of an investigative service may include expanding the use of an existing pathology test or diagnostic imaging modality (e.g. MRI) to a new group of patients currently on the MBS.

New (or change to existing) specific (single) consultation item

For specific consultative services, a single model of care is proposed to be the sole clinical encounter covered by the service. For these applications, it is feasible that health outcomes (directly or indirectly) can be measured via a HTA Framework. A previous example of this includes a consultation item that was proposed to solely cover patient group sessions to manage diabetes, as opposed to the current model of care based on a one-on-one consultation between a doctor and the patient. In this instance, a clinical comparison of health outcomes (both safety and clinical effectiveness) as well as a comparison of cost and clinical consequences (and thus a HTA) is feasible.

New (or change to existing) co-dependent investigative service with a drug

This includes co-dependent applications that require a HTA through the MSAC process (this does not include the type of co-dependent applications identified in part d [non-HTA consideration] below). A co-dependency occurs where the use of one health technology (e.g. a

medicine, or medical device or procedure) is improved by the use of another health technology (e.g. pathology or an imaging diagnostic technology) providing optimal clinical and economic performance. Examples include:

- Where a therapeutic medical service involves a medicine requiring consideration by the Pharmaceutical Benefits Advisory Committee (PBAC) and the co-dependent investigative service (for example, biomarker, imaging, etc.) requires a separate consideration by MSAC.
- Where co-dependent investigative and therapeutic medical services are both being considered for potential MBS funding requiring the clinical merits of both to be considered by MSAC only.

New (or change to existing) MBS item reflecting who can deliver a specific clinical service

These applications primarily comprise requests from a health professional group for specific access to a service on the MBS (including a new service) so they can provide the same clinical service already provided by other types of health professionals. Provided such applications have been found appropriate for consideration by MSAC (see **Section 5.1.1** above), the main issue for MSAC when considering comparative safety, effectiveness and cost-effectiveness of this category of application, is whether the same service rendered by the different health professional groups would result in similar or different patient health outcomes. These applications are often accompanied by clinical claims by the health professional group in question, that the nature and level of their training is such that they provide at least equivalent care compared to other health professional groups providing the service. However, this type of application can be challenging to assess as there is often a lack of research that aims to primarily assess the impact on health outcomes of one health professional group delivering a specific clinical services compared to another health professional group. That said, where evidence (be it direct or indirect) is available, a clinical comparison of health outcomes (both safety and clinical effectiveness) as well as a comparison of cost and clinical consequences is feasible. However, in the absence of any evidence from the outset supporting the clinical claim of the applicant, a decision will need to be made whether commencing a HTA`through the MSAC process will be an efficient and effective use of tax payers money against the principles of the *PGPA Act 2013* (see **Section 5.1.1**)**.**

For these types of applications that have been identified as needing a HTA, PASC consideration is necessary and is the next stage in the process. This is examined further in **Section 5.2**.

<u>Applications which may warrant consideration through an alternate (non-HTA) pathway</u>

The following application principles may warrant consideration through an alternate (non-HTA) pathway:

- Non-material in nature (either financially or administratively).
- HTA is being conducted primarily by another committee, alongside MSAC (i.e. through the PBAC).
- The use of a HTA approach is simply not feasible because of the difficulty of measuring (directly or indirectly) the net impact of the clinical health outcomes of the proposal.

Figure 9 referred to earlier provides the decision flowchart for dealing with applications which may not fit a HTA pathway and may therefore warrant consideration through a non-HTA

pathway such as direct consultation between the applicant, the Department and other relevant stakeholders. Application types that may fit this category are outlined in more detail below.

Some examples of application types that may not fit a HTA pathway are as follows:

a) Financial change only to an existing therapeutic or investigative service which is not accompanied by a clinical change

This type of application reflects where there is a change in the schedule fee(s) of an existing therapeutic or investigative MBS item but there is no material change in the clinical delivery of the service, in terms of how (technology/approach) and who (both who provides the service and who receives it). In this instance, there is only a material financial change and there is nothing to compare clinically, as the clinical service is essentially remaining the same. Irrespective of the quantum of the financial change in this scenario, the pathway forward for this category of application will be the same.

b) New (or change to existing) global consultation items

For applications to MSAC requesting new or changes to existing global attendance items that cover multiple clinical encounters (for example requests by particular health practitioner groups for increased funding), it is difficult to reliably quantify (even with a linked evidence approach) the incremental benefit of the health outcomes of funding the global consultation versus the status quo.

This is relevant if a number of factors, besides just a change in funding, could be influencing any health outcomes that are observed. If these other factors have not been adequately controlled and adjusted for ahead of time, it is near impossible to attribute any health outcome to how the global consultation is funded. However on the rare occasion if prospective evidence has in fact been generated that measures the specific impact of global consultation items (or the impact of other funding arrangements) on health outcomes then this category of application will be redirected down a HTA pathway.

c) New (or change to existing) co-dependent MBS item to cover the complex administration of a drug

A HTA paradigm may be unnecessary for co-dependent applications between MSAC and PBAC, where PBAC is assessing the merits of a drug (via a HTA) and MSAC considers the professional service for the administration of the drug. The vast majority of applications to PBAC do not require a separate listing on the MBS for the delivery of the drug, but occasionally there is a drug where the time and complexity of administering that drug warrants the creation of an accompanying MBS item (Botox being an example). In this situation, the accompanying professional service for the administration of the drug does not require a separate HTA to be conducted by MSAC to inform the MBS listing, alongside the HTA conducted by PBAC for the drug.

The above category of applications (refer to a, b and c) may progress, after endorsement of the MSAC Exec, straight to an internal utilisation and financial analysis conducted by the Department with the intention of representing this analysis to the MSAC Exec for consideration and approval at a later date (MSAC Exec meet ten times per year). Alternatively the MSAC Exec may recommend that this analysis be scrutinised by ESC and the full committee of MSAC if the application is associated with potentially large net changes in MBS expenditure if it were granted approval.

d) Non-material change, both financially and clinically, for therapeutic or investigative services

This type of application reflects a change to an existing item where there is no change in the schedule fee but only minor changes to the item descriptor that does not materially change how the service is clinically delivered. Examples of this non-material change include:

- Administrative amendments to an existing service description, such as clarification of the wording of an existing item descriptor without altering its intended use, or changing a service description addressing terminology that is not technically correct or ambiguous.
- A change that addresses a typographical error or to align an item descriptor with the regulations (e.g. inclusion of a missing word as a result of human error).
- a change that proposes to remove reference to brand names in an existing item descriptor and make the wording of the descriptor generic. In this situation the Department will need to ensure that by making an item descriptor more generic that it does not inadvertently allow clinical practice that is not intended to be covered by the item (be it technology or population creep).

For these applications, an internal assessment is conducted by the Department (application managers in consultation with the Policy Area and Advisers) to confirm that the proposal is in fact a non-material change.

These applications will proceed directly towards implementation analysis as a result of a decision within the Department (after endorsement from MSAC Exec), without further consideration through the MSAC application process.

4.2 Pathway element – PASC intensity

The second objective of segmentation is to determine the appropriate PASC pathway and therefore the extent of the development of a PICO. The appropriate PASC pathway is determined by analysing the: a) clinical novelty; and b) complexity of an application. In doing so, the Department will understand the application's resource effort required in progressing through the MSAC process - ensuring sustainability in the MSAC process into the future.

There are three proposed PASC pathway types:

- **Standard:** The 'standard' or default pathway for PASC is seen as the primary pathway in which the majority of applications will progress through. The standard pathway will generally involve the development of a PICO Confirmation by a HTA group; consideration at one PASC meeting[6], and development of an assessment report for consideration by ESC and MSAC.
- **Comprehensive:** Occasionally an application is received that requires the identification of more than two populations and/or comparators (e.g. screening programmes) and therefore the development (of a more detailed PICO Confirmation. The comprehensive pathway will follow the same steps as a standard pathway but will

[6] While one PASC consideration will be the norm for the standard pathway, PASC will always have the option to direct that the PICO Confirmation be considered at a subsequent meeting/s before approving its progression to ESC.

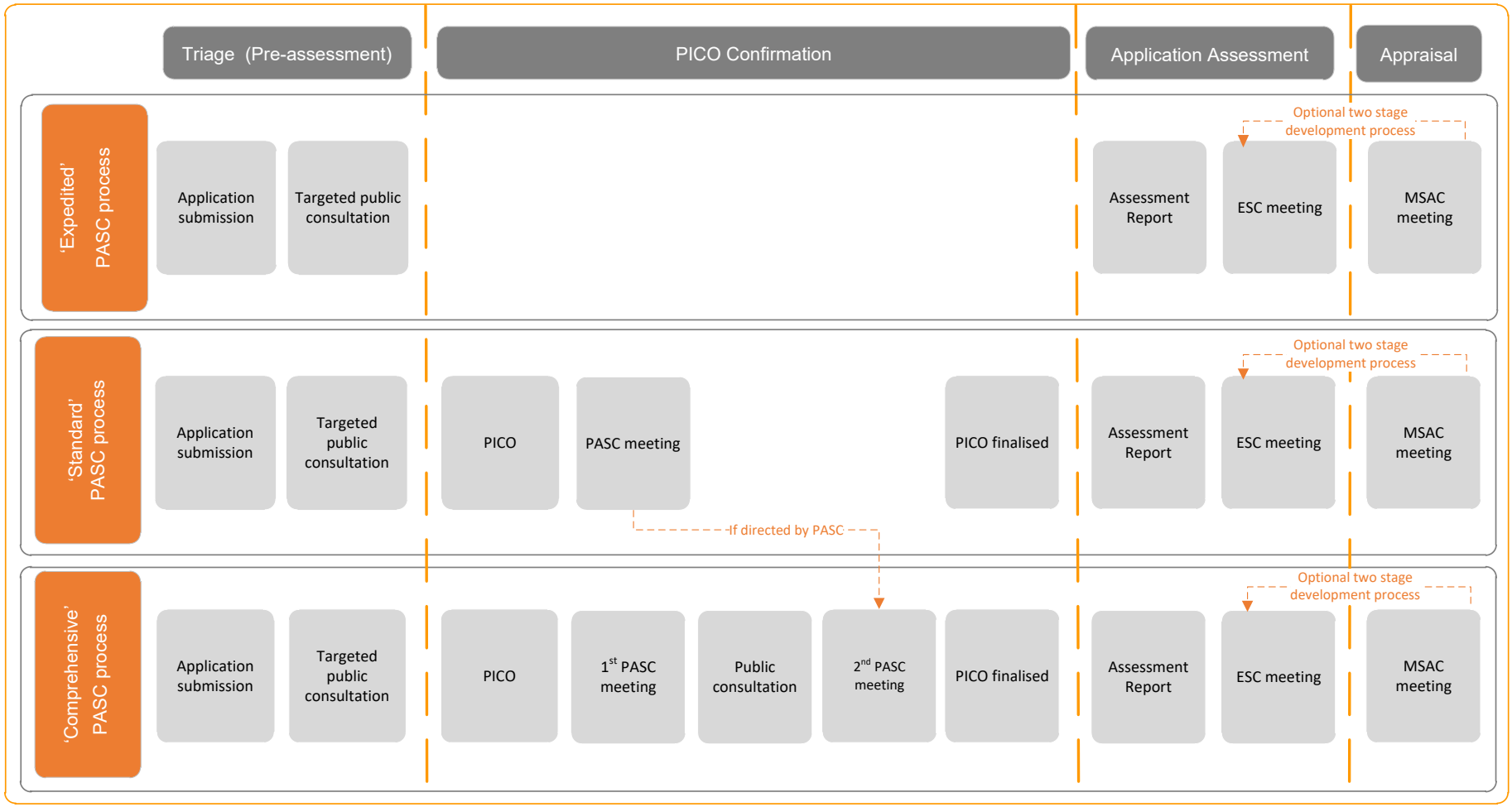
likely require more than one consideration be PASC [7]. This pathway will also have a formal public consultation period on the PICO confirmation between the two PASC meetings.

- **Expedited:** Occasionally an application's PICO will be very clear at the application form stage and therefore the Department and MSAC Exec may agree that the application can bypass PASC and progress straight to the development of an assessment report for ESC consideration or MSAC (dependant on the decision to be made).

The composition and process of each of the MSAC proposed pathways – expedited, standard and comprehensive are outlined in **Figure 10** below.

[7] While two PASC considerations will be the norm for the comprehensive pathway, PASC will have the discretion to approve an application's progression to ESC after one meeting.

Figure 10: MSAC proposed pathways



4.2.1 Clinical novelty

The first component to guide the determination of PASC pathways for applications that can be considered through a HTA framework is 'clinical novelty'. Over recent years both PASC and MSAC have seen enough 'pattern recognition' over a range of applications that there is likely to be a precedent from previous applications to identify if and the extent that PICOs need to be developed and thus flag opportunities to expedite the PICO stage of the process. While this pattern recognition can be classified in a variety of ways, for the purpose of this Framework it is classified via a high-level assessment of the clinical novelty of the application.

Low clinical novelty

Applications are considered low novelty if the following are observed:

- Amendment to an existing MBS item to accommodate the use of a technology or technique with characteristics that are similar to what is already covered in an existing service description. However, because of how the existing service description is worded it does not accommodate the use of the proposed technology/technique; and/or no change to the population(s) in the existing item, posing little to no risk of leakage to other populations not intended by the application.

- Minor changes to existing populations (see examples **Box 1**).

In the above circumstance, the proposed place of the application in terms of its point in the clinical pathway is easily identifiable, including identification of the comparator, which is referred to in the existing service descriptor. Applications considered low clinical novelty are likely to progress through an *expedited PASC process* because the development of the PICO is envisaged to be relatively straightforward and closely aligned to existing PICOs based on 'pattern recognition'. Examples of this type of application are identified in **Box 1** below.

Box 1: Low clinical novelty examples

An example of a 'low clinical novelty' application was a request to include the use of single balloon enteroscopy (Application 1206) in an existing item that already stipulated double balloon enteroscopy. In this instance both the comparator (double balloon enteroscopy) and the population (obscure gastrointestinal bleeding) was already referred to in the existing item descriptor, and there was not a proposal to change the target population for either the intervention or the comparator. The proposed change to the existing MBS item was to simply remove the word 'double' and refer to 'balloon enteroscopy', so the use of either single or double balloon enteroscopy (which are interchangeable in clinical practice) were both accommodated for under the MBS item.

An example of a minor population change would include broadening the intended use of an existing service within a medical condition to a new single patient population, that is currently not eligible for the service, but where the proposed new positioning of the service is simply a different position in the same clinical management pathway as the current population and thus the comparator will be more straight forward to identify. For example expanding the eligibility of a service as to when the service is used i.e. in addition to being used as a third line treatment the application is seeking to expand the use of the service *upstream* as a second line treatment for the medical condition.

High clinical novelty (default)

An application is considered to be of high novelty if it is proposing:

- The creation of a 'new' service altogether in the management of a particular medical condition.
- A major change to the population in the existing item, for example:
    (a) Broadening the intended use of an existing service to a new medical condition that is different altogether to the medical condition currently eligible under an existing item. In this instance, a new clinical management pathway needs to be identified and a discussion at PASC required to validate the exact position in the pathway (as well as what the appropriate comparator will be). For example, expanding the use of 'HER2' testing in gastric cancer in addition to breast cancer.
    (b) Broadening the intended use of an existing service within a medical condition to more than one new patient population that is currently not eligible for the service where more than one clinical management pathway for different clinical scenarios within a medical condition are required to be identified including a different comparator for each. For example expanding the use of Breast MRI that is currently available for asymptomatic women under 50 years who are at high risk of breast cancer to allow the use Breast MRI in a couple of additional breast cancer scenarios - (1) in those who are newly diagnosed with breast cancer to offer local staging when conventional imaging is likely to under stage the disease, and (2) for use in MRI guided biopsy in patients with suspected breast cancer where the lesion is only identifiable by MRI.

For these applications, the proposed place in the clinical pathway (and identification of relevant comparators) might not be immediately apparent. These applications will require at least one meeting of PASC to confirm that the proposed PICO and clinical pathway/s are correct.

4.2.2 Complexity

The second component to guide the determination of PASC pathways for applications that can be considered through a HTA framework is 'complexity'. This component assesses the level of complexity of applications that are considered high clinical novelty to inform whether one or two considerations by PASC may be required.

Occasionally an application is received that requires the identification of more than two populations (and comparators). A recent example was an MSAC application for magnetic resonance imaging of patients with suspected non-ischemic cardiomyopathies which required several distinct PICOs to be developed for five different populations being considered as part of the application. These types of applications are likely to require more than one consideration by PASC, will default down the comprehensive pathway and will require public consultation between both the period of the PASC meetings.

These types of applications are usually the exception, not the rule. For most applications it is anticipated that one PASC meeting should be sufficient, particularly for those which only involve one or two populations (and comparators). However, PASC will always have the option to direct that the PICO Confirmation be considered at a subsequent meeting/s before approving its progression to ESC.

4.3 Pathway element - Assessment requirements

The third objective of segmentation is to determine the assessment timing, assessment modelling complexity and other assessment complexities of an application (all detailed below). These components have implications for the preparation and structure of evidence outlined in each of the *Technical Guidelines for preparing Assessment Reports for the Medical Services Advisory Committee* (Technical Guidelines)[8], as well as the level of complexity of the modelling that needs to be presented to MSAC.

4.3.1 Assessment timing

This component provides a snapshot of the evidentiary landscape in terms of assessing the broad availability and status of the body of evidence/trials underpinning an application and the optimal timing of the anticipated progression of the application, specifically when it is to reach ESC and finally MSAC. This section also outlines the option of a two stage development process of the Assessment Report.

Evidence availability

This component is not intended to provide a detailed analysis of the *actual* body of evidence in question, what it is saying (or likely to say) or an appraisal of the merits of the evidence – which is the subject of ESC and MSAC consideration.

As noted above, the applicant will be responsible for providing a list of relevant evidence, in the Application Form, that they plan to use at the assessment report stage. The Department will then verify the availability of evidence and determine when it would be most appropriate for an assessment report to be developed. For example, if the final outcomes of a primary piece of evidence is identified as not being available for one year, the Department will recommend to the applicant that the application be put on hold until closer to the time in which the evidence will be available for consideration by MSAC and its subcommittees.

Categorising assessment report timing aims to identify, ahead of time, the likely availability of evidence by the time the application is to be considered by ESC and MSAC, including an assessment of key research that is in the 'evidentiary pipeline' that could be potentially critical for MSAC's consideration. It also attempts to measure the future timing of the evidence publication and whether this will be approximately aligned to the anticipated ESC and MSAC meeting dates. The updated application form to the Department will request information from the applicant in regards to the approximate timing of future evidence.

On receipt of an application, the Department will verify via a general search of key clinical trial databases and registries (such as www.clinicaltrials.gov) to ascertain when these studies are likely to have results approximately available.[9] Such databases and registries provide reporting on the progression of clinical trials in terms of its readiness for publication of results, the likely timing of the completion of trials and where the trial is being conducted. It also includes vital information on trial PICOs such as the patient population being studied and the study design of specific trials (including how patients have been recruited and analysed, comparators and the health outcomes that are proposed to be measured).

[8] Technical Guidelines relate to Investigative and Therapeutic services, published at: http://www.msac.gov.au/internet/msac/publishing.nsf/Content/publications-lp-1

[9] This information will be requested in the updated Application Form to the Department.

The likely time horizon of clinical evidence that will feed into any subsequent ESC consideration is also important to anticipate ahead of time. For example, in regards to the assessment of safety there will be more uncertainty with applications that state they are likely to have only six months to a year of follow-up data by the time MSAC considers the application compared to say three years of data. This is particularly important for applications that are associated with chronic conditions or interventions with significant associated morbidity and mortality where there is an expectation of longer follow-up safety data (for example Class III or AIMD devices as classified by the TGA).

If little evidence exists or the evidence is only in the early stages of being established and this is likely to remain the case for some time, then this flags it may not be an efficient and effective use of Government and committee resources to (potentially) prematurely present an application to the ESC/MSAC stages of the process. In this situation, the Department will advise the applicant that they are not ready for MSAC consideration and will advise of a suitable time to resubmit their application.

If the application specifically refers to data in the pipeline that may become available at a specific point in time then it may be reasonable to postpone the consideration of the application to suit the availability of the data.

The groupings of consideration for this component are outlined in **Box 2** on the following page.

Box 2: Groups of Assessment timing considerations (guide only)

Evidence available for consideration:

- Application is well advanced in terms of the evidentiary cycle with results from key trials (e.g. phase III) already publicly available. Real life observational data (e.g. in the form of registries) is also available to complement any trial data.
- Long-term data (greater than two years) on both benefits and safety is available for MSAC to consider.

Evidence might be available for consideration:

- Conduct of key trials supporting the application is well advanced and is nearing the end or has completed the recruitment phase suggesting data analysis is already occurring.
- The proposed publication date of provisional results (or in-confidence access to these results ahead of publication) is likely to be closely aligned with the proposed date of MSAC consideration but risk remains that there could be slippage in the timing of this data.
- Not clear whether real life observational data (e.g. in the form of registries) is also being collected to complement any trial data.
- Clinical data on both benefits and safety likely to be of only medium time horizon (between one to two years) by the time MSAC considers the application.

Evidence not available for consideration:

- Application has been presented early in the evidentiary cycle with only phase I/II trials currently being conducted; results of these trials will only be available by the time MSAC considers the application.
- The proposed publication date of the results of planned larger (phase III) trials is well beyond the date of the likely MSAC consideration and these larger trials are at most only in the recruitment phase.
- Not clear whether real life observational data is being collected to complement any trial data.
- Any longitudinal data that is available on both benefits and safety is only short-term in terms of time horizon (less than one year).

In summary, the consideration of the availability and timing of evidence, based on the information in **Box 2** above, will enable *indicative* ESC and MSAC meeting dates to be identified for each application. This will assist with planning purposes for the applicant, Department and committee schedules. The Department recognises that most applicants want their application/s to be considered for public funding by MSAC as soon as practically possible and that this may not always align with the maturity of the evidence base. If it is clear that an individual application that is proposed to be considered by ESC and MSAC on nominated dates is premature, then the Department will initiate a conversation with the applicant as to whether it is appropriate to proceed. It is anticipated that this will be an exceptional circumstance.

4.3.2 Optional two stage development of the Assessment Report

Information related to the Assessment Report composition is available in each of the Technical Guidelines (Therapeutic and Investigative) for preparing assessment reports to MSAC . Assessment Reports include the following sections outlined in **Table 3** below. A summary of the feedback from any formal public consultation (only for applications that are deemed comprehensive), as feedback that has been received throughout the process as well as a consumer impact statement is also drafted alongside the assessment report

Table 3: Assessment Report sections

Section	Extent of variation
Executive summary	Required for all
Section A – Context	Required for all
Section B – Clinical evaluation	Variation possible (see Technical Guidelines)
Section C – Translation issues	Links Sections B and D when Section D is required to be completed
Section D – Economic evaluation	Variation possible (refer to Section 5.3.2)
Section E – Financial implications	Required for all
Section F – Other	Optional

The Department received feedback from some applicants that they may prefer to submit the clinical component (Sections A and B) of their assessment report before commencing the economic component (Sections C to F) in order to have the benefit of ESC and MSAC's feedback on both the clinical evidence and proposed structure of the economic model. For example the applicant may wish to confirm the clinical component and seek advice regarding the appropriate economic model to use in the economic component.

It should be noted that in commencing this pathway it will require a two stage approach to their submission (i.e., will be considered by ESC and MSAC twice), the first stage presenting Sections A and B and the second stage presenting Sections C to F.

It is recommended that applicants consider submitting a draft financial component, Section E, alongside Sections A and B if they choose this two stage optional pathway.

If an applicant prefers this two stage option, this will be identified in the APR, noting that expected timeframes may be longer with this option, however may be more effective and efficient in the long run in the application's overall consideration.

Please refer to the factsheet on the MSAC website outing how a two stage development of the assessment report may work in practice.

4.3.3 Assessment modelling complexity

The aim of this part of the Process Framework is to flag what type of assessment modelling is required for each application (where relevant). This has implications for contracts with HTA groups and the length of time required to conduct and construct differing types of assessment reports.

Specific information relating to the associated modelling requirements of assessment reports is outlined in each of the Technical Guidelines (Section D).

Application consideration through a HTA pathway

For applications progressing through a HTA pathway (refer to **Section 4.1.2**) economic modelling will need to be conducted. Whether the net clinical benefit claimed is either no worse than the comparator (non-inferior) or better than the comparator (superior) will underpin how complex the economic modelling will need to be when considered by ESC/MSAC. This is expanded further in each of the Technical Guidelines for preparing assessment reports to MSAC.

If the applicant is making an assertion that the proposed medical service is superior to the main comparator (and provided the applicant can present clinical evidence to support their assertion), a cost-effectiveness analysis (CEA) or cost-utility analysis (CUA) is appropriate to determine whether the increase in health outcomes (and any cost offsets) justifies the medical service costs in terms of being acceptably cost-effective. Refer to the Technical Guidelines for preparing assessment reports to MSAC for information on which of these modelling requirements are required for relevant applications. If there are uncertainties and/or trade-offs across health outcomes (e.g. increased effectiveness and reduced safety or differing safety profiles), a cost-consequences analysis (CCA) is appropriate to present the results in a disaggregated way against the costs.

If the applicant is making an assertion that the proposed medical service is no worse than the main comparator (non-inferior), and provided the applicant can provide clinical evidence to support their assertion, a cost-minimisation analysis (CMA) is appropriate. In this instance the economic analysis is simplified, creating opportunities for the assessment report to take less time to develop and the ability to plan ahead for ESC consideration sooner.

Applications for services in relation to rare medical conditions ('rule of rescue')

The MSAC process recognises that for some applications (because of the rarity of the medical condition under consideration) both the volume and nature of evidence is such that it is difficult to undertake a traditional HTA. MSAC also recognises that for some medical conditions equity issues need to be considered.

Four factors, which apply in exceptional circumstances, are particularly influential in determining whether 'rule of rescue' applies. The four factors are as follows:

- No alternative exists in Australia to treat patients with the medical condition under consideration. This means that there are no suitable medical services for these patients.
- The medical condition is severe, progressive and expected to lead to premature death. The more severe the condition, the younger the age at which a person with the condition might die or the closer a person with the

condition is to death, the more influential the rule of rescue might be in the consideration by MSAC.

- The medical condition applies to only a very small number of patients. Again, the fewer the patients, the more influential the rule of rescue might be in the consideration by MSAC.
- The proposed medical service provides a worthwhile clinical improvement sufficient to qualify as a rescue from the medical condition. The greater the rescue, the more influential the rule of rescue might be in the consideration by MSAC.

Section F of the Technical Guidelines for preparing assessment reports to MSAC elaborates further on what to present in an assessment report if an application has all these four factors. The important message here is that the MSAC process is already flexible to accommodate the assessment of this circumstance in a fit for purpose way.

Application consideration through alternate (non-HTA) pathways

For those applications in which a clinical claim is not necessary to be tested by MSAC (an example being a co-dependency – refer to **Section 4.1.2**), no economic modelling is required. In this instance only an internal utilisation and financial analysis (equivalent to **Section E)** by the Department is required, including an analysis as to whether the proposed MBS fee is justified. Any recommendation made as a result of the MSAC Exec's (or the full committee of MSAC) consideration of the utilisation and financial analysis will be communicated to the applicant.

Deferring Assessment report to ESC/MSAC – base case changed to economic model post critique

In the circumstance where the base case of the economic model contained in an assessment report has been fundamentally changed post critique either to incorporate the effect of 'late hour' clinical evidence into the economic model (evidence that should have otherwise been anticipated ahead of time) or the base case has been changed to address specific comments in either an independent critique or the ESC Report, the proposed course of action in this instance would be to defer ESC/MSAC consideration to enable a third party to independently re critique the new base case of the revised economic model. In the absence of a new critique to inform deliberations of ESC/MSAC, ESC/MSAC will not be sufficiently confident in the revised economic model without a third party separately and forensically assessing the new model which would include a re characterisation of residual uncertainties associated with the model.

4.4 Pathway element – Mechanism

The fourth objective of segmentation is to determine (where relevant) whether the assessment report will be contracted or submission-based. A brief explanation of each is provided below.

Contracted: The Department organises, coordinates and covers the costs associated with developing and preparing the necessary MSAC documents for consideration. This includes the Department directly liaising with the HTA group regarding the requirements and timeframes, however, allowing the applicant to also engage with the HTA group via the Department.

Submission-based: The applicant is responsible for organising, coordinating and covering the costs associated with developing and preparing the necessary MSAC documents for consideration. In doing so they must consider the necessary requirements and timeframes.

The extent of the applicant's capacity and intention to satisfactorily conduct and engage in the requirements of each step of the MSAC process, in terms of compiling an assessment report (the latter prepared against the Technical Guidelines for preparing assessment reports to MSAC and utilising the assessment report template), will be considered and discussed between the Department and the applicant. It should be noted that although the applicant may indicate they would like to submit an SBA, the Department is still executing contracts to validate the evidence, therefore, the Department will make the final decision, aligning them with the PGPA Act.

Some decision factors for the Department and an applicant to consider include:

- Does the applicant satisfactorily understand the MSAC process, including the dependencies and requirements?
- Has the applicant gone through the MSAC process before?
- Does the applicant have the expertise or ability to engage a relevant HTA group to conduct the output (i.e. ability to develop an assessment report including conduct of clinical evaluations and/or economic evaluations etc.)?
- Does the applicant have the resources to conduct the output (e.g. money, time, capacity etc.)?
- Anything else determined as appropriate markers.

As part of the reformed MSAC process the PICO Confirmation will only be conducted on a contracted basis by a HTA group and there is no option for the development of a submission-based PICO Confirmation. Assessment Reports should be conducted against a PICO Confirmation that has been agreed to by PASC.

Co-dependent applications: Applicants seeking co-dependant MBS and PBS listings are encouraged to lodge with both MSAC and PBAC at the same time, noting that a co-dependent application must be submission-based.

4.5 Documentation

The fifth and final objective of segmentation is to ensure outcomes of relevant components of this Framework are summarised and documented in a standardised template format – the APR, for the applicant and all relevant stakeholders within the Department (application manager, Policy Area and Secretariat).

This APR will be:

- Initially conducted at the 'MSAC Triage (pre-assessment)' stage as an 'APR Creation'.
- Updated after the 'MSAC PICO Confirmation' stage as an 'APR check-point'.
- Finalised after the 'MSAC Appraisal' stage as an 'APR evaluation'.

Any changes identified through the APR check-point and evaluation are documented and kept as a historical reference in the APR. Refer to **Section 3** for further information on segmentation through the MSAC stages.

The APR includes:

- Basic application details (number, title, description, service type, applicant details, date submitted, associated resubmission details, etc.).
- Expected APR finalisation dates.
- Outputs of segmentation objectives (suitability, PASC intensity, assessment requirements, mechanism).
- MSAC process document dates.
- Committee meeting dates.
- Summary from MSAC committee meetings.

The use of an APR ensures:

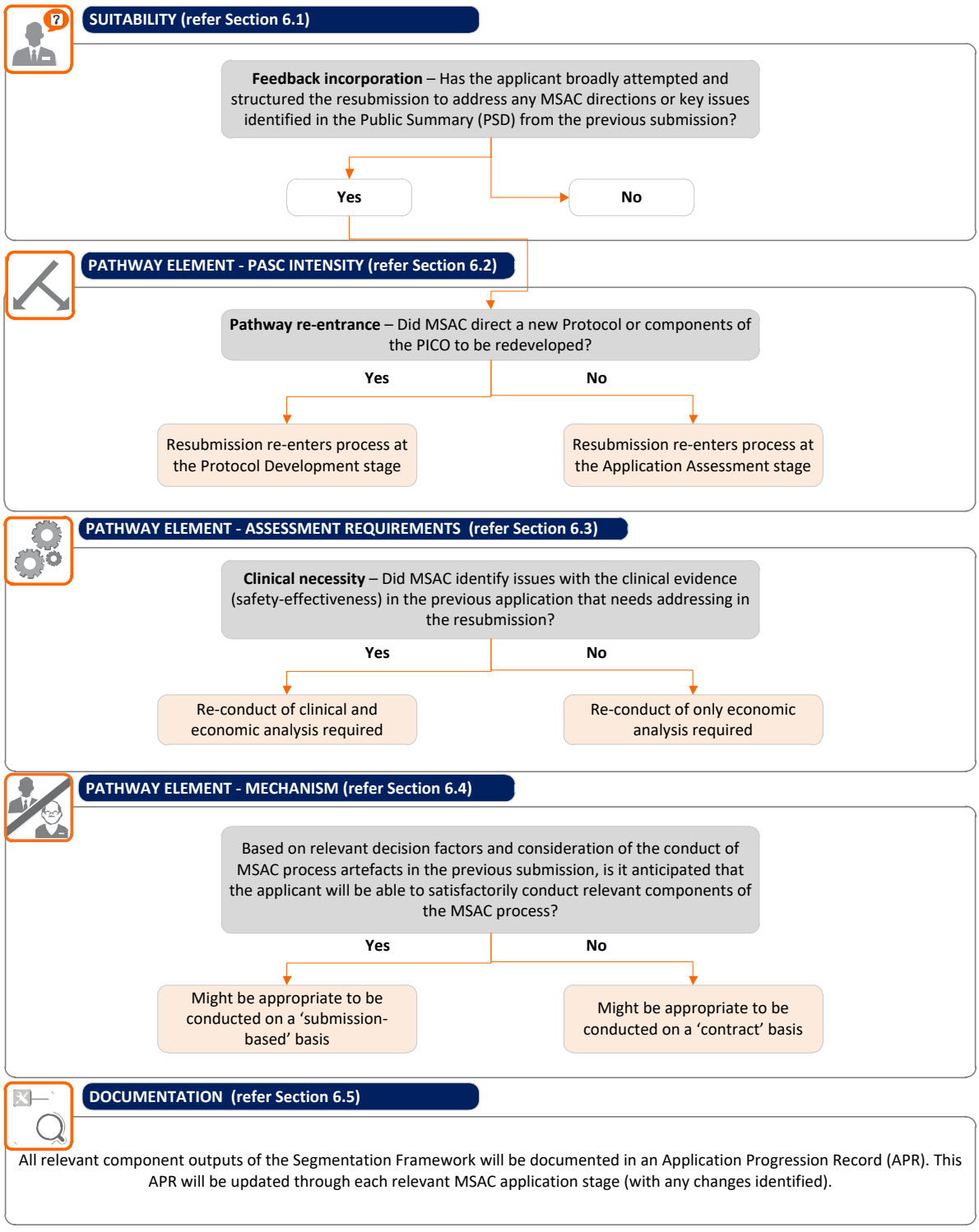
- Sufficient rationale which supports the decision-making in the process.
- Documentation and tracking of all high-level relevant application information.
- A feedback, monitoring and evaluation mechanism through the MSAC process.
- A central, complete and transparent communication mechanism.

Appendix 1 provides a draft APR template for new applications.

5 Segmentation objectives – resubmitted applications

This Section outlines the specific segmentation process and decision criteria for resubmitted applications. **Figure 11** provides a visual representation of the decision criteria flowchart in relation to resubmitted applications, which is explained further in this Section.

Figure 11: Decision criteria flowchart – Resubmitted



5.1 Suitability

For applications that have been resubmitted (i.e. resubmission of a separate, but linked application) following previous consideration by MSAC, there are opportunities for an expedited resubmission process where the application was unsuccessful in the previous submission. A resubmission may be required due to receiving a 'negative' or 'changes and reconsideration required' recommendation from MSAC and the grounds for resubmission are outlined in writing in the Public Summary Document (PSD) that is generated once MSAC has considered an application.

The PSD outlines the key issues and residual uncertainties that may have resulted in an application being unsuccessful in the previous submission. This document outlines which areas of evidence a resubmission must address and focus on, as well as outline any MSAC direction in terms of expectations of any subsequent resubmission.

As a first component, on receipt of a resubmission, the Department will undertake a high level assessment of the submitted documentation against the original PSD to determine whether the applicant has attempted to structure their resubmission to address the key issues identified in the PSD. Resubmissions that have broadly addressed (or attempted to address) recommendations are considered suitable for MSAC reconsideration. If the Department determines that the applicant has *not* broadly attempted to address MSAC recommendations, then the application is considered unsuitable for MSAC consideration (in its resubmitted current form) and will not be accepted by the Department until the appropriate changes have been made. This is in aligned with the Department's responsibilities under the ***PGPA Act 2013*** *(*refer to **section 5.1.1**) .

5.2 Pathway element – PASC intensity

The next component of the resubmission process is to determine which stage of the MSAC process the resubmission re-enters.

In the PSD, if MSAC previously identified issues with the previous PICO (or equivalent documentation) and specifically directed the application to be reconsidered by PASC then a new PICO Confirmation will need to be developed by a HTA group engaged by the Department in line with the reformed MSAC process. In this instance, the resubmission re-enters at the PASC stage of the process via a standard PASC process (with PASC directing a second meeting where required). If MSAC primarily identified issues with the evidence only, rather than the PICO Confirmation, then the application re-enters at the ESC stage.

5.3 Pathway element – Assessment requirements

The extent of assessment report requirements depends on the nature of the issues that MSAC identified with the previous application. If MSAC identified issues and uncertainties with the safety and effectiveness of the service under consideration and these were the main reasons why the application was unsuccessful previously, then a resubmission of the clinical analysis (Section B – primary evidence of the Assessment Report, refer to **Section 5.3.3**) is required. As the accompanying economic analysis is heavily reliant on the clinical analysis as an input, this will also need to be recompleted, along with financial analysis.

On the other hand, if an application was previously deficient only on cost-effectiveness aspects (not because of flaws in the clinical analysis) primarily due to how the economic analysis was conducted, including how the clinical evidence was translated into analysis, then a resubmission needs to only focus on an economic analysis being re-conducted (which may include the financial analysis). This obviously assumes that any underlying clinical evidence has not fundamentally shifted since MSAC's consideration of the previous application.

5.4 Pathway element - Mechanism

This component is similar to that of new applications, where consideration is given to how the assessment report (where relevant) will be generated, i.e., whether the assessment report for re-submission will be contracted or submission-based.

The only point of difference for resubmissions is that the generation of the previous assessment report will not necessarily dictate who will generate the new assessment report. For example, the previous application may have taken a submission-based approach, but a contracted approach (or vice-versa) may be more appropriate for the resubmission based on hindsight or consideration of the time required to prepare the previous application's documents. Refer to **Section 5.4** for associated information.

5.5 Documentation

This component is consistent to that of new applications, refer to **Section 5.5** for associated information.

Appendix 2 provides a draft APR template for resubmitted applications.

Appendix 1: Application Progression Record template – NEW applications

Application details

Application number:	<Number>	**Date submitted by applicant:**	<Date>
Is the application a resubmission?	<Yes or no> If Yes, date first submitted: <Date> If Yes, previous submission number: <Number>		
Reason for application:	<3 options>		
Application title:	<Free text>		
Description of medical service:	<Free text>		
Description of medical condition:	<Free text>		
Technology type:	<Options>	**Medical service type:**	<x options>
Interaction with linked committee?	<PBAC, PLAC, None>		
Applicant:	<Name and company of all applicants>		

Segmentation Application Progression Record confirmation (where relevant)

Pre-meeting with Applicant and Department	<Date>
Follow-up meeting(s) with Applicant and Department	<Date>
APR Creation - Agreed by Departmental Executive	<Date>
APR Creation - Agreed by Applicant	<Date>
APR check-point - Agreed by Departmental Executive	<Date>
APR check-point - Agreed by Applicant	<Date>
Debrief meeting with Applicant and Department	<Date>

APR creation - Triage stage

Segmentation assessment at Triage stage.

Part	Component	Result
Suitability	Appropriate for MSAC consideration?	<Yes – aligns to MBS, Yes – Ministerial direction, No>
	Necessity for HTA Framework?	<Yes, No>
	Necessity for HTA Framework comments	<Free text>
	Suitability outcome: <Not suitable, Expedited PASC pathway, PASC intensity consideration, Department implementation>	
	Suitability outcome comments: <Free text>	
Pathway element – PASC	Clinical novelty – extent the application is proposing a new service or change to existing service	<Default – Med/High, Low>

Part	Component	Result
intensity	Complexity – identification of more than two populations and/or comparators	<Yes, No>
	PASC intensity	<Expedited, Standard, Comprehensive>
	PASC intensity comments: <Free text>	
Pathway element – Assessment requirements	Availability and timing of evidence for consideration?	<Evidence available for consideration, Evidence might be available for consideration, Evidence not available for consideration>
	Optional two-stage development of the Assessment Report?	<Yes, No>
	Assessment modelling complexity?	<Identify type>
	Other Assessment complexities comments: <Free text>	
Pathway element – mechanism	Assessment report	<Submission-based, Contracted>
	Name of HTA group for Assessment report development or critique	<name>

APR check-point – after PICO Development stage

Segmentation changes occurring from the Triage stage.

Associated rationale for change: <Free text>		
Part	**Component**	**Result**
Pathway element – Assessment requirements	Availability and timing of evidence for consideration?	<Evidence available for consideration, Evidence might be available for consideration, Evidence not available for consideration>
	Optional two-stage development of the Assessment Report?	<Yes, No>
	Economic modelling complexity?	<Identify type>
	Other Assessment complexities: <Free text>	
Pathway element – mechanism	Assessment report	<Submission-based, Contracted>
	Name of HTA group for Assessment report development or critique	<name>

APR evaluation – after Appraisal stage

Final Segmentation assessment after Appraisal stage.

Part	Component	Result
Suitability	Appropriate for MSAC consideration?	<Yes – aligned to MBS, Yes – Ministerial direction, No>
	Necessity for HTA Framework?	<Yes, No>

Part	Component	Result
	Suitability outcome: <Not suitable, Expedited PASC pathway, PASC intensity consideration, Department implementation>	
	Suitability outcome comments: <Free text>	
Pathway element – PASC intensity	PASC intensity	<Expedited, Standard, Comprehensive>
	PASC intensity comments: <Free text>	
Pathway element – Assessment requirements	Availability and timing of evidence for consideration?	<Evidence was available for consideration, Evidence was partly available for consideration, Evidence was not available for consideration>
	Optional two-stage development of the Assessment Report?	<Yes, No>
	Assessment modelling complexity?	<Identify type>
	Other Assessment complexities: <Free text>	
Pathway element – mechanism	Assessment report	<Submission-based, Contracted>
	Name of HTA group for Assessment report development or critique	<name>

Artefact finalisation dates (if relevant)

Public consultation commencement	<Date>
PICO (or equivalent)	<Date>
Assessment report	
Public Summary Document	<Date>

Committee meeting dates (if required)

	PICO Advisory Sub-Committee (PASC)	Evaluation Sub-Committee (ESC)	Medical Services Advisory Committee (MSAC)
At Triage stage (APR Creation) - *anticipated*	<Date>	<Date>	<Date>
At Appraisal stage (APR Evaluation) - *actual*	<Date>	<Date>	<Date>

Summary from committee meetings (if relevant)

PASC	<brief text>
ESC	<brief text>
MSAC	<brief text>
Other relevant notes	<brief text>

Appendix 2: Application Progression Record template – RESUBMITTED applications

DRAFT APPLICATION PROGRESSION RECORD TEMPLATE – RESUBMITTED APPLICATIONS

Application details

Application number:	<number>	**Date submitted by applicant:**	<dd/mm/yy>
Resubmission details:	Date first submitted: <Date> Previous submission number: <Number>		
Reason for application:	<3 options>		
Application title:	<Free text>		
Description of medical service:	<Free text>		
Description of medical condition:	<Free text>		
Technology type:	<Options>	**Medical service type:**	<x options>
Interaction with linked committee?	<PBAC, PLAC, None>		
Applicant:	< Name and company of all applicants>		

Segmentation Application Progression Record confirmation (where relevant)

Pre-meeting with Applicant and Department	<Date>
Follow-up meeting(s) with Applicant and Department	<Date>
APR Creation - Agreed by Departmental Executive	<Date>
APR Creation - Agreed by Applicant	<Date>
APR check-point - Agreed by Departmental Executive	<Date>
APR check-point - Agreed by Applicant	<Date>
Debrief meeting with Applicant and Department	<Date>

APR creation - Triage stage

Segmentation assessment at Triage stage.

Part	**Component**	**Result**
Suitability	MSAC direction incorporated?	<Yes, Maybe, No>
	Suitability comments: <Free text>	
Pathway element – PASC intensity	Pathway re-entrance – did MSAC direct a new PICO to be developed?	<Yes, No>
	PASC intensity	<Resubmission re-enters at PASC stage, Resubmission re-enters at ESC stage>
	PASC intensity comments: <Free text>	

Part	Component	Result
Pathway element – Assessment requirements	Clinical necessity – did MSAC identify issues with the clinical evidence in the previous application that needs addressing?	<Yes, No>
	Assessment modelling complexity?	<Re-conduct of clinical and economic analysis required, Re-conduct of only economic analysis required >
	Assessment requirements comments: <Free text>	
Pathway element – mechanism	Assessment report	<Submission-based, Contracted>
	Name of HTA group for Assessment report development or critique	<name>

APR check-point – after PICO Development stage

Segmentation changes occurring from the Triage stage.

Associated rationale for change: <Free text>		
Part	**Component**	**Result**
Pathway element – Assessment requirements	Clinical necessity – did MSAC identify issues with the clinical evidence in the previous application that needs addressing?	<Yes, Maybe, No>
	Assessment modelling complexity?	<Re-conduct of clinical and economic analysis required, Re-conduct of only economic analysis required >
	Assessment requirements comments: <Free text>	
Pathway element – mechanism	Assessment report	<Submission-based, Contracted>
	Name of HTA group for Assessment report development or critique	<name>

APR evaluation – after Appraisal stage

Final Segmentation assessment after Appraisal stage.

Part	Component	Result
Suitability	MSAC direction incorporated?	<Yes, Maybe, No>
	Suitability comments: <Free text>	
Pathway element – PASC intensity	Pathway re-entrance – did MSAC direct a new PICO to be developed?	<Yes, Maybe, No>
	PASC intensity	<Resubmission re-enters at PASC stage, Resubmission re-enters at ESC stage>
	PASC intensity comments: <Free text>	

Part	Component	Result
Pathway element – Assessment requirements	Clinical necessity – did MSAC identify issues with the clinical evidence in the previous application that needs addressing?	<Yes, Maybe, No>
	Assessment modelling complexity?	<Re-conduct of clinical and economic analysis required, Re-conduct of only economic analysis required >
	Assessment requirements comments: <Free text>	
Pathway element – mechanism	Assessment report	<Submission-based, Contracted>
	Name of HTA group for Assessment report development or critique	<name>

Artefact finalisation dates (if relevant)

Public consultation commencement	<Date>
PICO (or equivalent)	<Date>
Assessment report	
Public Summary Document	<Date>

Committee meeting dates (if required)

	PICO Advisory Sub-Committee (PASC)	Evaluation Sub-Committee (ESC)	Medical Services Advisory Committee (MSAC)
At Triage stage (APR Creation) - *anticipated*	<dd/mm/yy>	<dd/mm/yy>	<dd/mm/yy>
At Appraisal stage (APR Evaluation) - *actual*	<dd/mm/yy>	<dd/mm/yy>	<dd/mm/yy>

Summary from committee meetings (if relevant)

PASC	<brief text>
ESC	<brief text>
MSAC	<brief text>
Other relevant notes	<brief text>