Australian Government

Department of Health

Application Form: 1372.1

(New and Amended

Requests for Public Funding)

(Version 2.4)

This application form is to be completed for new and amended requests for public funding (including but not limited to the Medicare Benefits Schedule (MBS)). It describes the detailed information that the Australian Government Department of Health requires in order to determine whether a proposed medical service is suitable.

Please use this template, along with the associated Application Form Guidelines to prepare your application. Please complete all questions that are applicable to the proposed service, providing relevant information only. Applications not completed in full will not be accepted.

Should you require any further assistance, departmental staff are available through the Health Technology Assessment Team (HTA Team) on the contact numbers and email below to discuss the application form, or any other component of the Medical Services Advisory Committee process.

Phone: +61 2 6289 7550
Fax: +61 2 6289 5540
Email: hta@health.gov.au
Website: www.msac.gov.au

PART 1 – APPLICANT DETAILS

1. Applicant details (primary and alternative contacts)

Corporation / partnership details (where relevant): Royal Australian and New Zealand College of Radiologists (RANZCR)
Corporation name: Insert corporation name here
ABN: 37 000 029 863
Business trading name: Insert business trading name here

Primary contact name: REDACTED

Primary contact numbers
Business: REDACTED
Mobile: REDACTED
Email: REDACTED

Alternative contact name: Insert name of alternative contact here

Alternative contact numbers
Business: Insert business number here
Mobile: Insert mobile number here
Email: Insert email address here

2. (a) Are you a lobbyist acting on behalf of an Applicant?

☐ Yes
☒ No

(b) If yes, are you listed on the Register of Lobbyists?

☐ Yes
☐ No

PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

3. Application title

MRI of the liver for patients with colorectal carcinoma (CRC) with suspected hepatic metastases or patients with suspected hepatocellular carcinoma (HCC) for the purposes of staging.

4. Provide a succinct description of the medical condition relevant to the proposed service (no more than 150 words – further information will be requested at Part F of the Application Form)

The population of patients proposed to be eligible for the intervention (MRI of the liver) includes:

- patients with known CRC with suspected liver malignancy requiring characterisation who may require hepatic interventions; and
- patients with suspected HCC for the purposes of staging where:
  - prior imaging in the last 12 months has identified a hepatic lesion over 10mm; or
  - the patient has been assessed as having a Child-Pugh class A and B liver function.

5. Provide a succinct description of the proposed medical service (no more than 150 words – further information will be requested at Part 6 of the Application Form)

MRI utilises strong, uniform magnetic fields to investigate the anatomy, perfusion, tissue characterisation and function of different organs and systems within the human body.

MRI has advantages over ultrasound, computed tomography (CT), positron emission tomography (PET) in diagnosing focal liver masses. With a combination of basic T1 and T2 weighted sequences, diffusion weighted imaging (DWI), and hepatobiliary specific gadolinium contrast agents, most liver lesions can be diagnosed. Benign lesions, such as cysts and hemangiomas can be distinguished from malignant lesions

6. (a) Is this a request for MBS funding?

☒ Yes
☐ No

(b) If yes, is the medical service(s) proposed to be covered under an existing MBS item number(s) or is a new MBS item(s) being sought altogether?

☐ Amendment to existing MBS item(s)
☒ New MBS item(s)

(c) If an amendment to an existing item(s) is being sought, please list the relevant MBS item number(s) that are to be amended to include the proposed medical service:

N/A

(d) If an amendment to an existing item(s) is being sought, what is the nature of the amendment(s)?

i. ☐ An amendment to the way the service is clinically delivered under the existing item(s)
ii. ☐ An amendment to the patient population under the existing item(s)
iii. ☐ An amendment to the schedule fee of the existing item(s)
iv. ☐ An amendment to the time and complexity of an existing item(s)
v. ☐ Access to an existing item(s) by a different health practitioner group
vi. ☐ Minor amendments to the item descriptor that does not affect how the service is delivered
vii. ☐ An amendment to an existing specific single consultation item
viii. ☐ An amendment to an existing global consultation item(s)
ix. ☐ Other (please describe below):

(e) If a new item(s) is being requested, what is the nature of the change to the MBS being sought?

i. ☐ A new item which also seeks to allow access to the MBS for a specific health practitioner group
ii. ☒ A new item that is proposing a way of clinically delivering a service that is new to the MBS (in terms of new technology and / or population)
iii. ☐ A new item for a specific single consultation item
iv. ☐ A new item for a global consultation item(s)

(f) Is the proposed service seeking public funding other than the MBS?

☐ Yes
☒ No

(g) If yes, please advise:

N/A

7. What is the type of service:

☐ Therapeutic medical service
☒ Investigative medical service
☐ Single consultation medical service
☐ Global consultation medical service
☐ Allied health service
☐ Co-dependent technology
☐ Hybrid health technology

8. For investigative services, advise the specific purpose of performing the service *(which could be one or more of the following)*:

i. ☐ To be used as a screening tool in asymptomatic populations
ii. ☒ Assists in establishing a diagnosis in symptomatic patients
iii. **x** Provides information about prognosis
iv. ☐ Identifies a patient as suitable for therapy by predicting a variation in the effect of the therapy
v. ☐ Monitors a patient over time to assess treatment response and guide subsequent treatment decisions

9. Does your service rely on another medical product to achieve or to enhance its intended effect?

☐ Pharmaceutical / Biological
☐ Prosthesis or device
☒ No

10. (a) If the proposed service has a pharmaceutical component to it, is it already covered under an existing Pharmaceutical Benefits Scheme (PBS) listing?

☐ Yes
☐ No

(b) If yes, please list the relevant PBS item code(s):

N/A

(c) If no, is an application (submission) in the process of being considered by the Pharmaceutical Benefits Advisory Committee (PBAC)?

☐ Yes (please provide PBAC submission item number below)
☐ No

(d) If you are seeking both MBS and PBS listing, what is the trade name and generic name of the pharmaceutical?

Trade name:
Generic name:

11. (a) If the proposed service is dependent on the use of a prosthesis, is it already included on the Prostheses List?

☐ Yes
☒ No

(b) If yes, please provide the following information (where relevant):

Billing code(s):
Trade name of prostheses:
Clinical name of prostheses:
Other device components delivered as part of the service:

(c) If no, is an application in the process of being considered by a Clinical Advisory Group or the Prostheses List Advisory Committee (PLAC)?

☐ Yes
☐ No

(d) Are there any other sponsor(s) and / or manufacturer(s) that have a similar prosthesis or device component in the Australian market place which this application is relevant to?

☐ Yes
☐ No

(e) If yes, please provide the name(s) of the sponsor(s) and / or manufacturer(s):

N/A

12. Please identify any single and / or multi-use consumables delivered as part of the service?

Single use consumables: The service involves the use of hepatobiliary specific contrast agent which will require the creation of a 'modifying' MBS item which is to be claimed simultaneously with the proposed MRI item. In the previous submission it was identified that the most appropriate and commonly administered contrast agent for liver MRI scans was gadoxetate disodium, marketed as Primovist (Bayer Australia, Pymble NSW). This contrast agent is reported to be more expensive than standard contrast agents (previously stated as $280) but provides greater accuracy.

Multi-use consumables: N/A

PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

13. (a) If the proposed medical service involves the use of a medical device, in-vitro diagnostic test, pharmaceutical product, radioactive tracer or any other type of therapeutic good, please provide the following details:

Type of therapeutic good: Contrast Agent for diagnostic imaging (gadoexetate disodium)/Primovist
Manufacturer's name: Bayer Australia
Sponsor's name: as above

(b) Is the medical device classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?

☐ Class III
☐ AIMD
☒ N/A – listed as a medicine with TGA

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

☐ Yes (If yes, please provide supporting documentation as an attachment to this application form)
☒ No

(b) If no, has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?

X☐ Yes (if yes, please provide details below)
☐ No

ARTG listing, registration or inclusion number: 104381 (since 2004)
TGA approved indication(s), if applicable: This medicinal product is for diagnostic use only. PRIMOVIST is indicated for use in adults for the enhancement of magnetic resonance imaging (MRI) of focal liver lesion
TGA approved purpose(s), if applicable:

15. If the therapeutic good has not been listed, registered or included in the ARTG, is the therapeutic good in the process of being considered for inclusion by the TGA?

☐ Yes (please provide details below)
☐ No

Date of submission to TGA:
Estimated date by which TGA approval can be expected:
TGA Application ID:
TGA approved indication(s), if applicable:
TGA approved purpose(s), if applicable:

16. If the therapeutic good is not in the process of being considered for listing, registration or inclusion by the TGA, is an application to the TGA being prepared?

☐ Yes (please provide details below)
☐ No

Estimated date of submission to TGA:
Proposed indication(s), if applicable:
Proposed purpose(s), if applicable:

Comment – the classification of MRI machines used for liver imaging with the TGA have not changed since the last submission – see previous submission for details on regulatory status of MRI devices

PART 4 – SUMMARY OF EVIDENCE

17. **Provide an overview of all key journal articles or research published in the public domain related to the proposed service that is for your application (limiting these to the English language only).** ***Please do not attach full text articles, this is just intended to be a summary.*** Below prioritises recent published studies since MSAC 2015

	Type of study design*	**Title of journal article or research project (including any trial identifier or study lead if relevant)**	**Short description of research (max 50 words)****	**Website link to journal article or research (if available)**	**Date of publication*****
1.	Meta analysis	Hannah RF, Miloushev VZ et al, Comparative 13-year meta-analysis of the sensitivity and positive predictive value of ultrasound, CT, and MRI for detecting hepatocellular carcinoma, Abdominal Radiology 2016;41:71-90	compared the sensitivity and positive predictive value of a number of imaging modalities for the diagnosis of HCC. The investigators found that contrast enhanced CT and 'standard' MRI had similar sensitivity and PPV's however MRI using hepatobiliary contrast agents had a statistically significantly higher sensitivity and PPV.	www.ncbi.nlm.nih.gov/pubmed/26830614	2016

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
2.	Retrospective non randomised study	Rostambeigi N, et al, Effect of MRI Versus MDCT on Milan Criteria Scores and Liver Transplantation Eligibility, AJR 2016; 2016:726-733	Study showed a change management of patients with HCC being considered for liver transplantation in 14% compared with CT	www.ncbi.nlm.nih.gov/pubmed/26796867	2016
3.	Prospective study on consecutive patients	Wang JH, et al, Clinical Impact of Gadoxetic Acid-Enhanced Magnetic Resonance Imaging on Hepatoma Management: A Prospective Study, Digestive Dis and Sciences 2016;61(4):1197-1205	This study showed that MRI altered the Barcelona Liver Clinic (BCLC) Stage of patients with early HCC in 27.8% and altered management in 18.9%	http://www.ncbi.nlm.nih.gov/pubmed/26668057	2016
4.	Economic Evaluation (generated overseas)	Lee JM, et al, Health economic evaluation of Gd-EOB-DTPA MRI vs ECCM-MRI and multidetector computed tomography in patients with suspected hepatocellular carcinoma in Thailand and South Korea, J Med Economics 2016; DOI: 10.3111/13696998.2016.1171230	Primovist liver MRI as the first diagnostic test in patients with suspected HCC shown to be cheaper than using either CT or MRI with extracellular gadolinium chelates	http://www.ncbi.nlm.nih.gov/pubmed/27026278	2016

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
5.	Within-trial cost evaluation (eight participating countries)	Zech CJ et al, Cost evaluation of gadoxetic acid-enhanced magnetic resonance imaging in the diagnosis of colorectal-cancer metastasis in the liver: Results from the VALUE trial, Eur Radiol. 2016 DOI 10.1007/s00330-016-4271-0	The diagnostic workup cost using MRI upfront resulted in costs savings compared to other diagnostic modalities (Nb- would need to be assessed for transferability of results to the Australian healthcare system)	http://www.ncbi.nlm.nih.gov/pubmed/26905871	2016
6.		.			
7.					
8.					

** Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.*

***Provide high level information including population numbers and whether patients are being recruited or in post-recruitment, including providing the trial registration number to allow for tracking purposes.*

**** If the publication is a follow-up to an initial publication, please advise.*

18. **Identify yet to be published research that may have results available in the near future that could be relevant in the consideration of your application by MSAC (limiting these to the English language only).** ***Please do not attach full text articles, this is just intended to be a summary.***

Comment – need to confirm with applicant whether any ongoing trials on this that may be published in the near future that is relevant

	Type of study design*	**Title of research (including any trial identifier if relevant)**	**Short description of research (max 50 words)****	**Website link to research (if available)**	**Date*****
1.	For yet to be published research that may have results relevant to your application, insert the type of study design in this column and columns below	For yet to be published research that may have results relevant to your application, insert the title of research (including any trial identifier if relevant) in this column and columns below	For yet to be published research that may have results relevant to your application, insert a short description of research (max 50 words) in this column and columns below	For yet to be published research that may have results relevant to your application, insert a website link to this research (if available) in this column and columns below	For yet to be published research that may have results relevant to your application, insert date in this column and columns below
2.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
3.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
4.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
5.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
6.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
7.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
8.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
9.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date

	Type of study design*	Title of research (including any trial identifier if relevant)	Short description of research (max 50 words)**	Website link to research (if available)	Date***
10.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
11.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
12.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
13.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
14.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
15.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date

** Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.*

***Provide high level information including population numbers and whether patients are being recruited or in post-recruitment.*

****Date of when results will be made available (to the best of your knowledge).*

PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

19. **List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the service (please attach a statement of clinical relevance from each group nominated):**

    Royal Australian and New Zealand College of Radiologists

    Advice provided by Dr Anthony Moore, medical adviser Department of Health (teleconference 24 August 2016) is that a statement of clinical relevance is not required for this resubmission given the new populations contained in this resubmission are subgroups within the broader populations considered in the previous submission (rather than an entire new population not considered previously) and only a statement of clinical relevance is required for a resubmission if an entirely new population was proposed that was not considered in the previous submission. The professional body is also the applicant but other professional bodies relevant for this reconsideration are those who represent requesters of the test (RACP/RACS)

20. **List any professional bodies / organisations that may be impacted by this medical service (i.e. those who provide the comparator service):**

    As per above

21. **List the relevant consumer organisations relevant to the proposed medical service (please attach a letter of support for each consumer organisation nominated):**

    As per identified last time during public consultation during the PASC stage

22. **List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed medical service:**

    N/A

23. **Nominate two experts who could be approached about the proposed medical service and the current clinical management of the service(s):**

    Name of expert 1: REDACTED

    Telephone number(s): REDACTED

    Email address: REDACTED

    Justification of expertise: REDACTED

    Name of expert 2: REDACTED

    Telephone number(s): REDACTED

    Email address: REDACTED

    Justification of expertise: REDACTED

    Please note that the Department may also consult with other referrers, proceduralists and disease specialists to obtain their insight.

PART 6 – POPULATION (AND PRIOR TESTS), INDICATION, COMPARATOR, OUTCOME (PICO)

PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION

24. Define the medical condition, including providing information on the natural history of the condition and a high level summary of associated burden of disease in terms of both morbidity and mortality:

This has been covered in the previous submission. Application 1372 was seeking the addition of MRI of the liver onto the MBS for two indications:

- Patients with known extrahepatic malignancy who are being considered by a specialist for hepatic therapies (including but not limited to percutaneous ablation, resection or transplantation); and
- Patients with known focal liver lesions requiring characterisation.

MSAC has previously indicated that there may be value in exploring the addition of MRI of the liver in the below population of patients:

- known colorectal carcinoma with suspected or possible liver metastases who are being considered by a specialist; or
- HCC identified by MRI for staging and management

This resubmission will aim to articulate the clinical utility of liver MRI in the populations suggested by MSAC which are more narrow populations within the broader populations considered in the previous submission.

25. Specify any characteristics of patients with the medical condition, or suspected of, who are proposed to be eligible for the proposed medical service, including any details of how a patient would be investigated, managed and referred within the Australian health care system in the lead up to being considered eligible for the service:

This has been covered in the past submission

26. Define and summarise the current clinical management pathway *before* patients would be eligible for the proposed medical service (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway up to this point):

This has remain largely unchanged since the last submission (see Assessment report and PSD for Application 1372)

PART 6b – INFORMATION ABOUT THE INTERVENTION

27. Describe the key components and clinical steps involved in delivering the proposed medical service:

Nil change since previous submission

28. Does the proposed medical service include a registered trademark component with characteristics that distinguishes it from other similar health components?

Nil change since previous submission

29. If the proposed medical service has a prosthesis or device component to it, does it involve a new approach towards managing a particular sub-group of the population with the specific medical condition?

N/A

30. If applicable, are there any limitations on the provision of the proposed medical service delivered to the patient (i.e. accessibility, dosage, quantity, duration or frequency):

The provision of liver MRI services, including machine eligibility as well as requirements for reporting/accreditation will be subjected to existing rules that govern the Diagnostic Imaging Services Table (DIST) of the MBS

31. If applicable, identify any healthcare resources or other medical services that would need to be delivered <u>at the same time</u> as the proposed medical service:

Specific contrast agents (and sometimes sedation)

32. If applicable, advise which health professionals will primarily deliver the proposed service:

Radiologists

33. If applicable, advise whether the proposed medical service could be delegated or referred to another professional for delivery:

N/A

34. If applicable, specify any proposed limitations on who might deliver the proposed medical service, or who might provide a referral for it:

This submission will focus on only specialist referral for MRI of the liver while the previous submission had a proposal to create an item for GP Referral.

35. If applicable, advise what type of training or qualifications would be required to perform the proposed service as well as any accreditation requirements to support service delivery:

Current legislative requirements stipulate that Medicare-eligible MRI items must be reported on by a trained and credentialed specialist in diagnostic radiology. The specialist radiologist must be able to satisfy the Chief Executive Medicare that they are a participant in the RANZCR Quality and Accreditation Program (Health Insurance Regulation 2013 – 2.5.4 – Eligible Providers) (Australian Government 2013). These legislative requirements will also apply to the proposed liver MRI item.

36. (a) Indicate the proposed setting(s) in which the proposed medical service will be delivered (select all relevant settings):

- ☒ Inpatient private hospital
- ☒ Inpatient public hospital
- ☒ Outpatient clinic (Radiology department for both inpatients and outpatients)
- ☐ Emergency Department
- ☐ Consulting rooms
- ☐ Day surgery centre
- ☐ Residential aged care facility
- ☐ Patient's home
- ☐ Laboratory
- ☐ Other – please specify below

Specify further details here

(b) Where the proposed medical service is provided in more than one setting, please describe the rationale related to each:

N/A

37. Is the proposed medical service intended to be entirely rendered in Australia?

- ☒ Yes
- ☐ No – please specify below

Specify further details here

PART 6c – INFORMATION ABOUT THE COMPARATOR(S)

38. Nominate the appropriate comparator(s) for the proposed medical service, i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system (including identifying health care resources that are needed to be delivered at the same time as the comparator service):

A range of existing tests are available for both the proposed populations in the absence of MRI of the liver:

- liver biopsy (also reference standard);
- multiphase computed tomography (CT) scan;
- contrast-enhanced ultrasound (CE-US); and
- intraoperative ultrasound (IOUS).

For the majority of patients, an MRI scan would most commonly be used as a replacement for multiphase CT scan. CT portography and positron emission tomography (PET) scans are not appropriate comparators, and are rarely used in Australia for this population.

Swings and roundabouts the comparators are largely unchanged since the past submission despite the further narrowing of the patient populations being put forward for consideration in this resubmission (which are effectively a subset of the broader populations considered last time).

39. Does the medical service that has been nominated as the comparator have an existing MBS item number(s)?

☒ Yes (please provide all relevant MBS item numbers - see below)
☐ No

- Multiphase abdominal CT scan (MBS items 56401 or 56507);
- CE-US scan (MBS items 55014 or 55016);
- biopsy (MBS item 30409); and
- N/B – no MBS item for intraoperative ultrasound.

40. Define and summarise the current clinical management pathways that patients may follow *after* they receive the medical service that has been nominated as the comparator (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway that patients may follow from the point of receiving the comparator onwards including health care resources):

The broad clinical management pathways for the two proposed populations remain largely unchanged compared to previous submission. Figure 1 and 2 in MSAC's Public Summary Document outlining the clinical management pathways for the broader patient populations considered in the last submission remain applicable for the proposed populations for the resubmission.

41. (a) Will the proposed medical service be used in addition to, or instead of, the nominated comparator(s)?

☒ Yes (will substitute)
☐ No

(b) If yes, please outline the extent of which the current service/comparator is expected to be substituted:

This was extensively canvassed in the assessment report of the last submission. Varying rates of substitution were tested in the calculation of the financial estimates in the past report. This will occur again this time.

42. Define and summarise how current clinical management pathways (from the point of service delivery onwards) are expected to change as a consequence of introducing the proposed medical service including variation in health care resources (Refer to Question 39 as baseline):

MRI liver is simply an alternate option for patients at relevant point in the clinical management pathway as per last submission. Despite more specific populations for this resubmission, the broader clinical management pathways, (including the proposed positioning of liver MRI in clinical management algorithms) have remained largely unchanged since the last submission.

The scenario where liver MRI is not used is now not the reality in the Australian health care system given that liver MRI is commonly requested already in the proposed populations in specialised centres but CT is still commonly ordered in areas where MRI is not available. MRI is performed in patients who can afford to pay for a non-rebatable scan. Public hospitals will fund some studies as they acknowledge the clinical utility of the examination.

PART 6d – INFORMATION ABOUT THE CLINICAL OUTCOME

43. Summarise the clinical claims for the proposed medical service against the appropriate comparator(s), in terms of consequences for health outcomes (comparative benefits and harms):

The clinical utility of MRI of the liver for the two proposed populations (as suggested by MSAC) is primarily based on new evidence that has been published in the past 12 months related to change in management arising from liver MRI as well a recent meta analyses (for HCC patients) that has reviewed the body of evidence on the relative accuracy of MRI liver vs other diagnostic imaging modalities.

MRI of the liver has the potential for substantial cost savings as it can prevent inappropriate intervention (both surgical, chemotherapeutic) and by correctly staging patients can reduce the number of repeat surgeries for early recurrence (ie patients with 'new' lesions that were present at the time of diagnosis but were not evident on less sensitive imaging methods (CT and PET/CT). This clinical claim in regards to incremental clinical utility (in terms of impact on health outcomes) of MRI of the liver relative to the comparators will be articulated through a linked evidence approach as recommended by the Investigative Guidelines.

Apart from using a narrower subset of the original population, the outcome measure being suggested in this assessment is different. The prior outcome measure seems to have been 'change in survival' however for a diagnostic test this would be better as 'change of management'.

44. Please advise if the overall clinical claim is for:

☒ Superiority
☐ Non-inferiority

45. Below, list the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be specifically measured in assessing the clinical claim of the proposed medical service versus the comparator:

Safety outcomes (largely covered in previous submission)

Adverse reaction to contrast agent
Cumulative effects of multiple contrast agent injections
Claustrophobia requiring the administration of sedation or general anaesthetic
Physical harms from follow-up testing
Other adverse events arising from liver MRI

Clinical effectiveness outcomes

Accuracy

- Sensitivity, specificity (confirmed by reference standard)
- Positive likelihood ratio, negative likelihood ratio (confirmed by reference standard)
- ROC curves
- Unsatisfactory uninterpretable test results

Change in management (Therapeutic efficacy)

- Change in treatment pathway (initiated, ceased, modified, avoided) – prevention of inappropriate intervention/reduced number in repeat surgery
- Avoidance of liver biopsy
- Avoidance of follow-up multi-phase CT imaging

Health outcomes (in the absence of direct evidence on health outcomes, linked evidence approach to assess the indirect impact of MRI on health outcomes will be attempted as per Investigative Guidelines)

- Liver disease-specific mortality rate

- Overall Survival
- Time to initial diagnosis
- Time from diagnosis to treatment
- Quality of life scores

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

46. Estimate the prevalence and/or incidence of the proposed population:

This has been covered in the previous submission

47. Estimate the number of times the proposed medical service(s) would be delivered to a patient per year:

Once for vast majority of patients

Follow-up MRI may be required for a minority of patients, for example when there is a time delay between the initial MRI scan and resection of a lesion (for example where surgery has been delayed by chemotherapy and an up to-date scan is required) and when patients have a hepatocellular carcinoma (HCC) that can only be seen on MRI and requires MRI for follow-up.

48. How many years would the proposed medical service(s) be required for the patient?

N/A

49. Estimate the projected number of patients who will utilise the proposed medical service(s) for the first full year:

This will be elaborated further in the assessment report. Because of the further narrowing of the populations compared to the previous submission, it is anticipated that the estimated utilisation will be slightly less than estimated in the original assessment report

50. Estimate the anticipated uptake of the proposed medical service over the next three years factoring in any constraints in the health system in meeting the needs of the proposed population (such as supply and demand factors) as well as provide commentary on risk of 'leakage' to populations not targeted by the service:

Given that liver MRI is already commonly ordered on this group of patients in highly specialised settings, specialists are already familiar with the requesting liver MRI. The risk of leakage to populations not targeted by the service is now diminished compared to previous submission because of the tighter definitions around which patient groups will be eligible.

The previous submission also requested a liver MRI item be created for GP referral (suggested at one of the early MSAC process meetings) but this resubmission is focused specialist referral only.

PART 8 – COST INFORMATION

51. Indicate the likely cost of providing the proposed medical service. Where possible, please provide overall cost and breakdown:

The proposed costs of the proposed service have remained unchanged since the past submission (base item + contrast item)

52. Specify how long the proposed medical service typically takes to perform:

Already outlined in previous submission

53. If public funding is sought through the MBS, please draft a proposed MBS item descriptor to define the population and medical service usage characteristics that would define eligibility for MBS funding.

Category 5 – DIAGNOSTIC IMAGING SERVICES
Item [proposed MBS item number 1] (specialist referral) MAGNETIC RESONANCE IMAGING performed under the professional supervision of an eligible provider at an eligible location where the patient is referred by a specialist or by a consultant physician – scan of liver for: - patients with known colorectal carcinoma with suspected or possible liver metastases who are being considered by a specialist for hepatic therapies (R) (Contrast), or - patients with suspected hepatocellular carcinoma (HCC) for the purposes of staging where: - prior imaging in the last 12 months has identified a hepatic lesion over 10mm; or - the patient has been assessed as having a Child-Pugh class A and B liver function. (R) (Contrast) (Anaes.) Bulk bill incentive Fee: $TBA: (See para DIQ of explanatory notes to this category)
Item [proposed MBS item number 2] NOTE: Benefits in Subgroup 22 are only payable for modifying items where claimed simultaneously with MRI services. Modifiers for sedation and anaesthesia may not be claimed for the same service. Modifying items for use with MAGNETIC RESONANCE IMAGING or MAGNETIC RESONANCE ANGIOGRAPHY performed under the professional supervision of an eligible provider at an eligible location where the service requested by a medical practitioner. Scan performed: - involves the use of HEPATOBILIARY SPECIFIC contrast agent for [proposed MBS item number 1] Bulk bill incentive Fee: $TBA

PART 9 – FEEDBACK

The Department is interested in your feedback.

54. How long did it take to complete the Application Form?

30 minutes

55. (a) Was the Application Form clear and easy to complete?

X☐ Yes
☐ No

(b) If no, provide areas of concern:

Describe areas of concern here

56. (a) Are the associated Guidelines to the Application Form useful?

☐ Yes
☐ No I didn't look.

(b) If no, what areas did you find not to be useful?

Insert feedback here

57. (a) Is there any information that the Department should consider in the future relating to the questions within the Application Form that is not contained in the Application Form?

☐ Yes
x☐ No

(b) If yes, please advise:

Insert feedback here