

Public Summary Document

Application 1683 - MRI of the liver, for the evaluation of hepatic metastases for initial staging or restaging prior to treatment using interventional techniques

Applicant: Department of Health

Date of MSAC consideration: MSAC 83rd Meeting, 25-26 November 2021

1. Purpose of application

To consider the financial implications of a recommendation from the Medicare Benefits Schedule (MBS) Review Taskforce - Diagnostic Imaging Clinical Committee (DICC) to create a new MBS item for magnetic resonance imaging (MRI) of the liver for initial staging or restaging of hepatic metastases prior to treatment using interventional techniques.

2. MSAC's advice to the Minister

After considering the estimated utilisation and financial impact of the MBS Review Taskforce - DICC's recommendation, MSAC supported MBS funding of MRI of the liver, for the evaluation of hepatic metastases for initial staging or restaging prior to treatment using interventional techniques. MSAC considered that MRI of the liver for the proposed population is best practice. MSAC advised that MBS item 63545, which is currently restricted to liver MRI in patients with colorectal cancer, be amended to allow MRI of the liver for patients with any oncological indication with suspected hepatic metastases. MSAC considered the utilisation and financial estimates were uncertain and advised that a review should be conducted in 5 years.

MSAC supported the following modifications to MBS 63545 item descriptor and fee:

MBS item 63545 (modified)

MRI – multiphase scans of liver (including delayed imaging, if performed) with a contrast agent, for staging where surgical resection or interventional techniques are under consideration to treat the liver metastases, if:

- (a) the patient has:
 - (i) a confirmed extra-hepatic malignancy, with absence of extra-hepatic disease (other than hepatocellular carcinoma); and
 - (ii) computed tomography, is negative or inconclusive, and the identification of liver metastases would change management.

For any particular patient—applicable not more than once in a 12 month period (R) (Contrast)

Bulk bill incentive

(Anaes.)

Fee: \$550.00 Benefit: 75% = \$412.50 85% = \$467.50

MBS item 63496 (modified)

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.

MRI service to which item 63544, 63545 or 63546 applies if:

- (a) the service is performed on a person under the supervision of an eligible provider; and
- (b) the service is performed using an hepatobiliary specific contrast agent.

Bulk bill incentive

Fee: \$250.00 Benefit: 75% = \$187.50 85% = \$212.50 (See para IN.0.19 of explanatory notes to this Category)

Consumer summary

This application was in response to a recommendation from the Medicare Benefits Schedule (MBS) Review Taskforce - Diagnostic Imaging Clinical Committee (DICC) to create a new MBS item for magnetic resonance imaging (MRI) of the liver for initial staging or restaging of hepatic metastases prior to treatment using interventional techniques.

MRI uses a powerful magnetic field, radio waves and a computer to produce detailed pictures of the inside of the body. MRI of the liver, to help diagnose or monitor treatment for a variety of conditions, including liver cancer, is currently MBS funded for patients with known colorectal cancer with suspected or proven liver metastases (cancerous tumours that have spread, or metastasised, to the liver; MBS item 63545) and patients with known or suspected hepatocellular carcinoma (a common type of liver cancer; MBS item 63546).

As part of a recent review of the MBS, the MBS Review Taskforce recommended that MRI of the liver should be MBS funded for all cancer patients with suspected or proven liver metastases.

MSAC discussed the estimated additional number of patients who would access a liver MRI if the service was expanded to all cancer patients with suspected or proven liver metastases, and the costs to the MBS of these additional scans. MSAC agreed that liver MRI to help diagnose or monitor treatment in these patients is best practice and therefore considered the estimated additional costs to the MBS to be reasonable. However, MSAC noted there was some uncertainty in the estimated number of patients who would access a liver MRI and recommended the utilisation be reviewed in 5 years.

MSAC's advice to the Commonwealth Minister for Health

MSAC supported MBS funding of MRI of the liver, for patients with any cancer type with suspected or proven liver metastases, for the evaluation of liver metastases for initial staging or restaging before treatment. MSAC recommended the utilisation of the MBS item be reviewed in 5 years.

3. Summary of consideration and rationale for MSAC's advice

MSAC noted the MBS Review Taskforce–DICC recommended creating a new MBS item for MRI of the liver for patients with any oncological condition, for the evaluation of hepatic metastases for initial staging or restaging prior to treatment using interventional techniques. MSAC recalled that it had previously supported MBS funding of liver MRI for two oncological populations: patients with known colorectal cancer (CRC) with suspected or proven liver metastases (MBS item 63545) and patients with known or suspected hepatocellular carcinoma (HCC; MBS item 63546). Following the advice of the MSAC Executive, application 1683 seeks MSAC advice on the potential utilisation and financial impact to the MBS as a result of creating a new MBS item for liver MRI for patients with any other oncological condition with suspected or proven liver metastases.

MSAC recalled it had previously accepted MRI of the liver as "a safe, non-invasive imaging technique for patients who are not contraindicated". MSAC agreed with the MBS Review Taskforce–DICC that liver MRI for diagnosis, initial staging and/or restaging prior to treatment is best practice for patients with any oncological condition with suspected or proven liver metastases (not just patients with CRC or HCC). MSAC also agreed that best practice should be encouraged through discussion with the patient, giving consideration to the value of input regarding patient management from a properly constituted multidisciplinary team (MDT). However, instead of creating a new MBS item, MSAC recommended that MBS item 63545 for liver MRI for patients with CRC be amended to include all oncological conditions.

MSAC noted that a market-share approach was used to estimate the utilisation and financial implications of funding liver MRI in patients with extra-hepatic primary tumours (non-CRC and non-HCC) with suspected liver metastases. MSAC noted the current utilisation of MBS item 63545 (liver MRI for patients with CRC) was used to 'scale up' and estimate the 'all other primary tumours' with liver metastases requiring an MRI based on the assumption that patients with CRC represents approximately 30% of all primary extra hepatic tumours. Based on this assumption, it was estimated that an additional 4,881 patients would receive a liver MRI in year 1, increasing to 6,230 patients in year 6. This would result in a total net cost to the MBS of \$20,513,946 over 6 years.

MSAC noted that the sensitivity analyses suggested the net cost to the MBS was sensitive to the upscaling estimates and could range from \$8,804,269 million to \$35,217,075 million over 6 years, if CRC is assumed to represent 50% or 80% of all primary extra hepatic tumours respectively. MSAC also noted the Department analysis on the actual utilisation of MRI for CRC (MBS item 63545) is significantly less than what was originally predicted. The predicted utilisation for Year 1 (2018–19) was 1,646 but the actual utilisation was 353. Similarly, the predicted utilisation in Year 3 (2020–21) was 10,889 but the actual utilisation was 2,095. Although, the estimates for expanding liver MRI to all other oncological conditions were based on the current (i.e. actual) utilisation of MBS item 63545 (2,095 in 2020-2021), MSAC noted there remained uncertainty in the estimated utilisation and financial impact to the MBS. Therefore, MSAC recommended the utilisation be reviewed 5 years after listing.

4. Background

MSAC has previously considered and supported MRI of the liver for patients with CRC with suspected hepatic metastases or patients with suspected HCC for the purposes of staging (<u>MSAC application 1372.1</u>).

In 2018, the MBS Review Taskforce – DICC agreed that a service is required for MRI of the liver for additional oncologic indications and recommended creating a new item for MRI of the liver for the evaluation of hepatic metastases for initial staging or restaging prior to treatment using interventional techniques (Recommendation 22, pg 109 of MBS Review Taskforce Final Report from the DICC Recommendations).

The DICC recommendation to create a new liver MRI item for all other oncological conditions was presented to the MSAC Executive in 2021. The MSAC Executive noted that the proposed liver MRI item could be used in a potentially large patient population and that information on the utilisation and potential net financial impact to the MBS should be presented to MSAC.

5. Prerequisites to implementation of any funding advice

MRI devices and contrast agents for clinical MRI are included on the Australian Register of Therapeutic Goods (ARTG).

6. Proposal for public funding

The proposed new MBS item for initial and restaging (Table 1) of suspected hepatic metastases in patients without CRC is presented below.

Table 1 Proposed new MBS item for MRI of the liver for initial and re-staging of suspected hepatic metastases prior to intervention, in patients without CRC or HCC

Category 5 - DIAGNOSTIC IMAGING SERVICES

MBS item XXXX

MRI – multiphase scans of liver (including delayed imaging, if performed) with a contrast agent, for initial and re-staging in patients with any cancer except colorectal cancer or hepatocellular carcinoma when:

- (a) known, suspected, or possible liver metastasis
- (b) computed tomography, or ultrasound imaging, has identified a mass lesion in patient's liver.
- (c) Patient referred by a specialist surgeon, oncologist, or radiation oncologist
- (d) Medicare benefits are only payable for this item if the service is provided to patients:
 - (i) For initial or re-staging prior to surgery, or
 - (ii) For initial or re-staging for treatment planning, or
 - (iii) for evaluation of suspected relapse based on pathology findings, or
 - (iv) when other imaging is inconclusive, or
 - (v) after consideration of patient's management at a properly constituted oncological multidisciplinary team meeting.

Fee: \$550.00 Benefit: 75% = \$412.50 85% = \$467.50

Source: Figure 1, pg 6 of MSAC 1683 Assessment Report

The proposed fee is based on the existing liver MRI MBS item 63545.

7. Population

The proposed population is patients with oncologic indications, with any extra hepatic primary cancer, excluding patients with CRC or HCC who are eligible for MBS items 63545 or 63546.

8. Comparator

The comparator for staging liver metastases in the proposed population is multiphase CT (MBS item 56407), PET (MBS item 61541 for colorectal carcinoma) or liver biopsy (MBS item 30409), where MRI of the liver would be an additional test for most patients. Multiphase CT scan (MBS item 56407) is currently used for patients with known CRC with suspected or possible liver malignancy and patients with suspected HCC. Liver biopsy (MBS item 30409) is currently used for patients with known CRC with suspected or possible liver malignancy. However, liver biopsy may not be appropriate to diagnose liver cancer due to the risk of spreading cancer cells outside the liver.1

Financial/budgetary impacts 9.

A market-share approach was used to estimate the use and financial impact of liver MRI in the defined new population. The estimated utilisation was based on the following assumptions:

- The current utilisation of MBS item 63545 (liver MRI for patients with CRC) reflects the staging and restaging of patients with liver metastases from CRC primary tumour
- The epidemiology of liver metastases (Horn 20201) indicates that most of the liver metastases had primary tumours in the gastrointestinal system:
 - 27% being colorectal in origin.
- Approximately 70% of extra hepatic primary cancers come from locations other than CRC.
- The upscaling factor: 70% / 30% = 2.33.

The utilisation and financial implications of MRI resulting from the proposed listing are summarised in Table 2.

¹ Horn, SR et al. (2020) Cancer epidemiology. 67:101760.

Table 2 Estimated use and cost of liver MRI in 'all other oncology cohort' (excluding CRC and HCC MRI patients)

Parameter	Year 1 2021	Year 2 2022	Year 3 2023	Year 4 2024	Year 5 2025	Year 6 2026
Staging of non CRC/HCC patients with liver metastasis						
MRI services	4,881	5,125	5,382	5,651	5,933	6,230
CT and US services	4,881	5,125	5,382	5,651	5,933	6,230
Comparator						
CT and US services	4,881	5,125	5,382	5,651	5,933	6,230
Financial impact to the MBS (non CRC/HCC patients with liver metastasis)						
MRI cost	\$3,015,908	\$3,166,704	\$3,325,039	\$3,491,291	\$3,665,856	\$3,849,148
CT and US cost a	\$2,177,857	\$2,286,750	\$2,401,087	\$2,521,142	\$2,647,199	\$2,779,559
Sub Total	\$5,193,765	\$5,453,454	\$5,726,126	\$6,012,433	\$6,313,054	\$6,628,707
Comparator						
CT and US cost a	\$2,177,857	\$2,286,750	\$2,401,087	\$2,521,142	\$2,647,199	\$2,779,559
Net cost to the MBS	\$3,015,908	\$3,166,704	\$3,325,039	\$3,491,291	\$3,665,856	\$3,849,148

Source: Table 1, pg 7 of MSAC 1683 Assessment Report

Abbreviations: CT, computed tomography; CRC, Colorectal carcinoma; HCC, Hepatocellular carcinoma; LM, liver metastases; MBS, medical benefits schedule; MRI, magnetic resonance imaging; US, Ultrasound

Note: non CRC/HCC patient are proxy for 'all other oncology cohort'

Table 2 displays the estimated number of MRI services and financial impact of liver MRI in the 'all other extra hepatic tumours cohort' (i.e. excluding CRC and HCC MRI patients). The estimated MRI service ranged from 4,881 in Year 1 increasing to 6,230 in Year 6. The estimated net cost to the MBS ranged from \$3,015,908 in Year 1 increasing to \$3,849,148 in Year 6. The 6-year cost to the MBS for listing liver MRI for staging of all other primary tumour patients (i.e. non CRC/HCC patients) with liver metastases is estimated to be \$20,513,946.

Sensitivity analyses were undertaken to explore the assumptions used for the base case financial estimates. The sensitivity analyses suggested that the net cost to the MBS was sensitive to the upscaling estimates and could range between \$8,804,269 million to \$35,217,075 million over 6 years (50% of those with liver metastases have CRC to 20% with liver metastases have CRC respectively).

^a CT and US is an equally weighted price (bundled price). As CT is in both arms there is no difference to cost. Base case considered to be same. CT and US include PET in the weighted (bundled) price as individual patient level data is unavailable. The bundled price was weighted up and down by 20% it doesn't change as off set is in both arms (see sensitivity analysis).

Six Year Total Cost to MBS

Base case
85% MBS Fee
20% lower cost
20% higher cost
80% non CRC
50% non CRC
No Growth
\$0 \$10,000,000 \$20,000,000 \$30,000,000

Figure 1 Six-year total cost to the MBS of this new MRI Liver listing

Source: Figure 6, pg 21 of MSAC 1683 Assessment Report

10. Other relevant information

Nil

11. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website: visit the MSAC website