

Chapter 1

Terms of Reference

1.1 On 1 November 2012, the Senate referred the following matters to the Finance and Public Administration References Committee (the committee) for report by the first sitting day of 2013:

- (a) the withdrawal of Medicare funding for Hyperbaric Oxygen Treatment (HBOT) of problem wounds and ulcers in non-diabetics (MBS Item number 13015), which will commence on 1 November 2012;
- (b) the Medical Services Advisory Committee (MSAC) process regarding this withdrawal, and other changes to the Medicare Benefits Schedule;
- (c) the costs/benefits of this withdrawal in relation to associated treatments for these medical conditions; and
- (d) any related matters.¹

Conduct of the inquiry

1.2 The inquiry was advertised in *The Australian* and through the Internet. The committee invited submissions from interested organisations and individuals, and government bodies.

1.3 The committee received 41 submissions. A list of individuals and organisations which made public submissions to the inquiry, together with other information authorised for publication by the committee, is at Appendix 1. The committee held one public hearing in Melbourne on 12 November 2012. A list of the witnesses who gave evidence at the public hearing is available at Appendix 2.

1.4 Submissions, additional information and the Hansard transcript of evidence may be accessed through the committee's website at www.aph.gov.au/senate_fpa. The committee thanks those organisations and individuals who made submissions and gave evidence at the public hearings.

Background to the inquiry

Hyperbaric Oxygen Treatment (HBOT)

1.5 Pressurisation treatments related to HBOT were first experimented with around 400 years ago in Britain and subsequently in Europe. While debate over the effectiveness of such treatments was common, a pressurised six storey hospital was

1 *Journals of the Senate*, No. 121, 1 November 2012, p. 3241.

built in 1928, but later decommissioned.² The use of HBOT for treating decompression sickness is widely known, however, many other applications have also been found, including treating gas gangrene, carbon monoxide poisoning and wound healing.³

1.6 The basic principles of HBOT can be summarised as follows. While most oxygen carried in the blood is bound to hemoglobin, some oxygen, however, is carried in solution, and this portion is increased under hyperbaric conditions. Administering 100 per cent oxygen increases the amount of oxygen dissolved in the blood and because the oxygen is in solution, it can reach areas where red blood cells may not be able to pass. It can also provide tissue oxygenation thereby assisting with healing. In practice, HBOT treatments often involve the patient being administered oxygen in either single person (monoplace) or multiplace chambers.⁴

1.7 In addition, there are also several other physiological effects that can potentially assist healing, such as displacement of cellular toxins, enhancements of immune processes and increased growth of new blood vessels.⁵

The Medical Service Advisory Committee (MSAC)

1.8 MSAC was established in 1998 as an independent scientific committee to improve health outcomes by ensuring that new and existing medical procedures attracting funding under the Medicare Benefits Schedule (MBS) are supported by evidence of their safety, clinical effectiveness and cost-effectiveness. The membership of MSAC includes individuals with expertise in clinical medicine, health economics and consumer matters. The MSAC website indicated that:

MSAC has the capacity to assemble and review available evidence. In some circumstances, MSAC can recommend interim funding to enable data collection, within an agreed research framework, in order to establish the evidence base.

Evaluation of evidence associated with medical services has been an integral part of the process for the listing of new medical technologies and services on the Medicare Benefits Schedule (MBS).⁶

-
- 2 Medscape reference, *Hyperbaric Oxygen Therapy*, <http://emedicine.medscape.com/article/1464149-overview>, (accessed 5 November 2012).
 - 3 Wikipedia, *Hyperbaric medicine*, <http://en.wikipedia.org/wiki/HBOT>, (accessed 5 November 2012).
 - 4 Medscape reference, *Hyperbaric Oxygen Therapy*, <http://emedicine.medscape.com/article/1464149-overview>, (accessed 5 November 2012).
 - 5 Hyperbaric Health, *Hyperbaric Oxygen Therapy*, www.hyperbarichealth.com/doc/hyperbarichealth-therapy-booklet.pdf, (accessed 5 November 2012).
 - 6 Medical Services Advisory Committee, <http://www.msac.gov.au/internet/msac/publishing.nsf/Content/about-us-lp-1>, (accessed 5 November 2012).

Medicare funding of HBOT and MSAC assessments

1.9 Medicare funding for HBOT became available in 1984. Following the establishment of MSAC in April 1998, HBOT for treatment of wounds and ulcers for non-diabetic patients has been reviewed. The following provides a timeline of the MSAC reviews.

Table 1.1: Timeline of MSAC considerations of non-diabetic HBOT⁷

1984	When Medicare and the Medicare Benefits Schedule were established a range of HBOT services were included. ⁸
1999	A manufacturer of monoplace (single person) hyperbaric chambers applied to MSAC to have a separate Medicare item number added to the MBS. ⁹ The application was to expand it from multichambers to monochambers. ¹⁰
August 2000	1018-1020 First formal MSAC consideration of HBOT. MSAC recommended continuation of funding for diabetic wounds and necrotising soft tissue infections, in relation to other indications. The report also concluded that there is currently insufficient evidence pertaining to HBOT use in several indications listed below. The MSAC recommended that public funding should not be supported for HBOT administered in either a multiplace or monoplace chamber, for: non-diabetic wounds, soft tissue radionecrosis, and a range of other conditions.
9 February 2001	The MSAC 1018-1020 advice not to fund HBOT for non-diabetic wounds, soft tissue radionecrosis was accepted by the Minister for Health and Aged Care. 'The then-Minister later decided that access to the use of HBOT for these indications would be maintained through the MBS on an interim basis.' The Department of Health and Ageing noted that this provided for an extended period during which comprehensive evidence could be gathered by the applicants to assess its safety and effectiveness compared with conventional wound care.
December 2001	Application for HBOT 1054 review received by MSAC. ¹¹

7 Unless otherwise indicated, the information is from Department of Health and Ageing *Submission 15*.

8 Ms Prue Power, Chief Executive Officer, Australian Healthcare and Hospital Association, *Committee Hansard*, 12 November 2012, p. 16.

9 Associate Professor David Smart and Associate Professor Mike Bennett, *Submission 18*, p. 3.

10 Dr Megan Keaney, Acting Assistant Secretary, Medical Specialist Services Branch, Medical Benefits Division, Department of Health and Ageing, *Committee Hansard*, 12 November 2012, p. 43.

11 Medical Services Advisory Committee, *Application 1054 - Hyperbaric oxygen therapy for the treatment of non-healing, refractory wounds in non-diabetic patients and refractory soft tissue radiation injuries*, <http://www.msac.gov.au/internet/msac/publishing.nsf/Content/app1054-1>, (accessed 8 November 2012).

May and November 2003	MSAC 1054 second formal assessment of HBOT. 'The clinical evidence was inadequate to substantiate claims that hyperbaric oxygen therapy (HBOT) was cost-effective in the treatment of refractory soft tissue injuries or non-diabetic refractory wounds. However, the MSAC recommended that as there are no effective alternative therapies and in view of the progress of local data collections and an international trial, funding for HBOT continue for MBS listed indications at current eligible sites for a further three years.'
31 August 2004	MSAC 1054 assessment endorsed by the Minister for Health and Ageing.
4 February 2010	Application for HBOT 1054.1 review received by MSAC. ¹²
1 January 2011	Reforms to MSAC process introduced. ¹³
8 September 2011	Final draft advisory panel report sent to MSAC advisory panel members. ¹⁴
4 October 2011	Dissenting report made to the 1054.1 assessment advisory panel's report. ¹⁵
12–13 October 2011	The Evaluation sub-committee considered the 1054.1 assessment. ¹⁶
29 November 2011	MSAC 1054.1 third formal assessment of HBOT. The report stated that: 'After considering the strength of the available evidence in relation to the safety, effectiveness and cost-effectiveness of HBOT Therapy for the treatment of chronic non-diabetic wounds MSAC does not support public funding for this indication on the basis of insufficient evidence.'
30 April 2012	Minister noted MSAC's advice in the 1054.1 assessment.

-
- 12 Medical Services Advisory Committee, *1054.1 – Review of Interim Funded Service: Hyperbaric Oxygen Treatment (HBOT)*, <http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1054.1>, (accessed 8 November 2012).
- 13 Department of Health and Ageing, *Submission 15*, p. 4.
- 14 Michael Bennett and David Smart, *Dissenting Report in relation to MSAC assessment 1054.1: Hyperbaric therapy for the treatment of chronic non-diabetic wounds and non-neurological soft tissue radiation*, 4 October 2011, p. 1.
- 15 Michael Bennett and David Smart, *Dissenting Report in relation to MSAC assessment 1054.1: Hyperbaric therapy for the treatment of chronic non-diabetic wounds and non-neurological soft tissue radiation*, 4 October 2011, p. 1.
- 16 Medical Services Advisory Committee, *1054.1 – Review of Interim Funded Service: Hyperbaric Oxygen Treatment (HBOT)*, <http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1054.1>, (accessed 8 November 2012).

8 May 2012	The 2012–13 Commonwealth Budget changed the Medicare funding arrangements for HBOT, with the descriptor for the MBS item for HBOT amended to remove the treatment of non-diabetic, chronic wounds. ¹⁷
16 July 2012	An application was lodged with new information and a summary of the concerns with the previous advice was received.
2 August 2012	Reconsideration of the 1054.1 assessment by MSAC. The new information was insufficient to change its previous advice, MSAC unanimously affirmed its advice to government. The submission by the Department of Health and Ageing states that: <p style="text-align: center;">In seeking a review, the applicants ignored MSAC's Public Summary Document, outlining the rationale for their reaffirmed advice, and continued to contest the Assessment Report.</p>
5, 10 and 13 September 2012	Meetings were held with Hyperbaric Health and other interested parties. ¹⁸
17 September 2012	Dr Hawkins, Hyperbaric Health, provided a submission to MSAC outlining the concerns of the affected parties about the cuts to Medicare funding. ¹⁹
September – October 2012	The Government commissioned the National Health and Medical Research Council (NHMRC) to review MSAC's assessment of HBOT for non-diabetic wounds: 'NHMRC considered how MSAC prioritised the evidence for assessment, and noted that weighting the Hammarlund and Sundberg (1994) RCT more heavily than the ANZHMG non-comparative wound study, was entirely appropriate. NHMRC further noted that this consideration of the evidence is in line with best practice evidence assessment and the NHMRC's own publications on consideration of evidence...The applicants and Hyperbaric Health were contacted on 12 October and this information was passed to them.' ²⁰
31 October 2012	The decision to change to the Medicare descriptor is implemented by the Health Insurance (General Medical Service Table) Amendment Regulation 2012 (No. 4) which was tabled in the Senate and House of Representatives. ²¹

17 Department of Human Services, *Budget 2012–13: Medicare Benefits Schedule – New and Revised listings*, <http://www.humanservices.gov.au/corporate/publications-and-resources/budget/1213/measures/health-matters/60139>, (accessed 6 November 2012).

18 Department of Health and Ageing, *Submission 15*, p. 7.

19 Dr Glen Hawkins, *Submission 4*, Attachment 2.

20 Department of Health and Ageing, *Submission 15*, p. 7.

21 *Journals of the Senate*, No. 120, 31 October 2012, p. 3224; *House of Representatives Votes and Proceedings*, No. 141, 31 October 2012, p. 1942.

1 November 2012	The Health Insurance (General Medical Service Table) Amendment Regulation 2012 (No. 4) came into effect and Medicare funding for HBOT for non-diabetic wounds ceased. ²²
-----------------	---

22 <http://www.comlaw.gov.au/Details/F2012L02103>, (accessed 19 November 2012).