SUBMISSION BY
THE AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH AND AGEING TO THE SENATE FINANCE AND PUBLIC ADMINISTRATION COMMITTEE'S INQUIRY INTO MEDICARE FUNDING FOR HYPERBARIC OXYGEN TREATMENT

1. Preamble

On 31 October 2012, Senators Xenophon, Fierravanti-Wells, Di Natale and Madigan moved that the following matters be referred to the Finance and Public Administration Committee for inquiry and report by 29 November 2012:

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

2. Summary

HBOT for the treatment of chronic non-diabetic wounds has been interim funded though Medicare since its first assessment by the MSAC in 2001. This allowed 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.

It was always intended that the use of HBOT for the management of chronic non-diabetic wounds be reviewed to determine whether the evidence justified ongoing public funding. The review was completed and MSAC considered the evidence in November 2011.

The unanimous advice to government from MSAC was that HBOT for chronic non-diabetic wounds is no more clinically effective than conventional wound care. MSAC reaffirmed its primary reliance on the single randomised controlled trial conducted in this field, which did not demonstrate any statistically significant difference in wound size between HBOT and placebo 18 weeks after treatment.

On the basis of that advice, in the 2012-13 Budget the Australian Government announced that Medicare funding of HBOT for chronic non-diabetic wounds would cease on 1 November 2012.

In August 2012, MSAC affirmed its advice to government, again unanimously, after it considered a further submission from the applicants. 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.

In October 2012, in response to further issues raised by the applicants, the Government commissioned a further review from the National Health and Medical Research Council

(NHMRC) of MSAC's assessment of the available evidence. NHMRC endorsed the approach taken by the MSAC.

Throughout the MSAC process, the HBOT industry has had many opportunities to provide new relevant information to MSAC. The applicants have had more than a decade of interim MBS funding to conduct a randomised controlled trial that could demonstrate long-term effectiveness, but have not done so. Meanwhile, more than $11 million in Medicare benefits has been paid through the interim item, which covers treatment for chronic wounds or soft tissue radionecrosis.

As a result of the ongoing lack of evidence of clinical effectiveness for this indication, MSAC did not support continuation of interim funding for this indication for a further indeterminate period, and noted that while the applicants had commenced recruiting for a randomised controlled trial, difficulties in recruitment suggest the proposed three-year timeframe for completion of the trial will not be met.

Effectively, the applicants are seeking a continuation of interim funding, to more than fifteen years, on the basis of evidence which was insufficient at MSAC's first consideration in 2001. If the HBOT industry believes it has new or additional evidence another application can be submitted to MSAC at any time.

It is also worth noting the views of the Cochrane Collaboration on HBOT. The Cochrane Collaboration is an international not-for-profit organisation that prepares, maintains and promotes the accessibility of systematic reviews of the effects of health care. It reviewed all the available international evidence and in 2012 drew a conclusion consistent with MSAC – that more evidence was needed to establish the true extent of the effectiveness of HBOT in patients with chronic non-diabetic wounds.

In addition, the Australian and New Zealand Clinical Practice Guideline for Prevention of Venous Leg Ulcers, published in October 2011 by the Australian Wound Management Association and New Zealand Wound Care Society, noted that there was insufficient evidence to recommend treatment with HBOT for patients with venous leg ulcers, the most common type of chronic non-diabetic wound.

In the last financial year, the Government invested $17.64 billion in Medicare benefits - about an average of $778 in Medicare benefits for every Australian. MSAC's evaluation of the evidence and its advice to government ensures that services funded though Medicare are safe and effective.

Medicare rebates for HBOT will continue to be available for conditions where the evidence demonstrates it is effective. MSAC has advised that the evidence demonstrates that HBOT is effective for wounds that follow radiotherapy treatment, diabetic wounds and decompression illness – so Medicare support for those conditions continues.

3. Role of MSAC

The principal role of MSAC is to advise the Australian Minister for Health and Ageing on evidence relating to the safety, effectiveness and cost-effectiveness of new medical technologies and procedures. This advice informs Australian Government decisions about public funding for new, and in some cases existing, medical procedures.

4. How MSAC operates

Purpose

The MSAC is an independent scientific committee comprising individuals with expertise in clinical medicine, health economics and consumer matters. It advises the Minister for Health on whether a new medical service should be publicly funded based on an assessment of its comparative safety, effectiveness, cost-effectiveness and total cost, using the best available evidence. This process ensures that Australians have access to medical services that have been shown to be safe and clinically effective, as well as representing value for money for the Australian health care system.

MSAC advises the Minister for Health on medical services including those that involve new or emerging technologies and procedures and, where relevant, amendment to existing MBS items, in relation to:

- the strength of evidence in relation to the comparative safety, effectiveness, cost-effectiveness and total cost of the medical service;
- whether public funding should be supported for the medical service and, if so, the circumstances under which public funding should be supported; and
- the proposed MBS item descriptor and fee for the service where funding through the MBS is supported.

The current members of MSAC are:

Member	**Expertise**
MSAC Executive	
Professor Robyn Ward (Chair)	Medical Oncology
Dr Frederick Khafagi (Deputy Chair)	Nuclear Medicine and Endocrinology
Professor Jim Butler (Chair Evaluation Sub-Committee)	Health Economics
Professor Andrew Wilson* (Chair Protocol Advisory Sub-Committee)	Public Health Medicine and Epidemiology
MSAC Members	
Associate Professor John Atherton	Cardiology
Associate Professor Michael Bilous	Anatomical Pathology
Professor Chris Baggoley	Commonwealth Chief Medical Officer *(ex officio member)*
Associate Professor Kirsty Douglas	General Practice/Research
Professor Kwun Fong	Thoracic and Sleep Medicine
Professor Paul Glasziou	Evidence-based Health care
Mr Scott Jansson	Medical scientist (pathology)
Professor David Little	Orthopaedics
Mr Russell McGowan	Healthcare Consumer
Professor David Roder	Public Health Medicine/Epidemiology
Associate Professor Bev Rowbotham	Haematology
Dr Graeme Suthers	Genetics/Pathology
Dr Simon Towler	AHMAC nominee *(ex officio member)*, Western Australia Chief Medical Officer, part-time Intensivist
Dr Christine Tippett	Obstetrics/Gynaecology
Associate Professor David Winlaw	Paediatric Cardiothoracic Surgery

Deliverables
The rationale for MSAC's advice to the Minister (or AHMAC where the matter has been referred through AHMAC arrangements) is provided in the form of a Public Summary Document.

5. Recent changes in the MSAC processes

A number of reviews have explored ways to improve the processes for assessing health technologies and services. Most recently, the Review of Health Technology Assessment in Australia (HTA Review) which reported to government in December 2009 aimed to address the regulatory burden on businesses that results from HTA processes, to ensure that those processes are efficient, measured and proportionate. The Review focussed on HTA processes performed by the Therapeutic Goods Administration (TGA), the Prostheses List Advisory Committee (PLAC), Pharmaceutical Benefits Advisory Committee (PBAC) and the MSAC – including co-dependent technologies that may go through more than one of these processes.

Since 2010, in response to the HTA Review, the Australian Government has undertaken a comprehensive overhaul of the management and governance processes relating to the MBS. Key reforms to the MSAC assessment process were introduced on 1 January 2011 and included new terms of reference for MSAC and the establishment of two sub-committees; the Protocol Advisory Sub-Committee (PASC) and the Evaluation Sub-Committee (ESC) and moving from Advisory Panels to standing subcommittees to better separate the role of advocates for a medical service and sources of expert advice.

The importance of MSAC's assessment of evidence was reinforced in the 2011 Budget through the announcement of the Comprehensive Management Framework for the MBS (CMFM). Under the CMFM, MSAC not only provides advice on new medical services involving technologies and procedures, but on all proposed changes to the MBS. The MSAC process ensures that applicants, stakeholders and the general public have ample opportunity to provide input into the assessment.

6. MSAC and HBOT

MSAC has assessed the safety, effectiveness and cost-effectiveness of HBOT on four occasions.

6.1 MSAC assessment 1018-1020

Prior to 2001, treatment with HBOT for non-diabetic wounds and soft tissue radionecrosis had received ongoing public funding through the MBS. Conducted in 2000, MSAC assessment 1018-1020 examined the safety, effectiveness and cost-effectiveness of HBOT treatment across a diverse range of indications (MSAC 2001). This assessment concluded that insufficient or conflicting evidence was found for the use of HBOT for treatment of non-diabetic wounds and soft tissue radionecrosis. On 9 February 2001, the Minister for Health and Ageing accepted MSAC's recommendation that 'public funding should not be supported for HBOT administered in either a multiplace or monoplace chamber' (MSAC 2001, p. 93) for the treatment of non-diabetic wounds and soft tissue radionecrosis. 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.

6.2 MSAC assessment 1054

In 2002, MSAC commenced re-assessing the interim listing of HBOT for safety, effectiveness, and cost-effectiveness, specifically as a secondary therapy for non-healing wounds in non-diabetic patients and in refractory soft tissue radiation injuries. This review incorporated new evidence generated since the initial review, including a small number of randomised controlled trial (RCT) studies providing moderate level II evidence. The assessment reported some clinical benefit for HBOT; positive clinical results were found regarding healing of otherwise non-healing wounds in non-diabetic patients, healing of tooth socket wounds following extraction from irradiated tissue, and reduction of healing complications in soft tissue grafts into irradiated tissue. However, MSAC concluded that the clinical evidence was inadequate to substantiate claims that HBOT was cost-effective in the treatment of non-healing wounds in non-diabetic patients and in refractory soft tissue radiation injuries.

From this assessment MSAC recommended that, in the absence of effective alternative therapies and in view of the progress of local data collections and an international trial, funding for HBOT should continue for existing MBS listed indications at eligible sites for a further three years. This recommendation was accepted by the Minister for Health and Ageing on 31 August 2004.

6.3 Assessment 1054.1 – November 2011

This assessment included and re-evaluated all relevant evidence regarding the safety, effectiveness and cost-effectiveness of HBOT for the treatment of chronic non-diabetic wounds and non-neurological soft tissue radiation injury. It took into consideration the findings of the two previous publications.

MSAC primarily relied on the only available randomised placebo-controlled trial of HBOT in 16 patients (8 patients in each group) with chronic non-diabetic leg ulcers not responding to other treatment for at least two months (Hammarlund and Sundberg, 1994) as the strongest evidence of comparative clinical effectiveness. MSAC noted that the other case series data, including data collected in Australia during the period of interim funding on the MBS, did not represent stronger evidence because these case series data were non-comparative.

The results of the Hammarlund and Sundberg (1994) trial indicated a statistically significant difference in the reduction in wound size at the end of six weeks of treatment. This initial difference was of little impact, however, as at 18 weeks after treatment, the difference was no longer statistically significant. MSAC noted that a more convincing outcome would have been complete resolution of the wound and concluded that these results provided weak evidence in relation to any additional overall clinical effectiveness of HBOT over usual treatment.

MSAC concluded that adding HBOT is more expensive than usual care in these patients. MSAC concluded that this extra expenditure was not justified by the weak evidence of additional clinical effectiveness.

MSAC considered that continuing interim funding would not serve a useful purpose because providing further opportunities to generate any more convincing comparative data was unlikely to be successful.

7. Interaction with the Applicants after the announcement of the outcome of the MSAC Evaluation

In May 2012, the government accepted advice from the November 2011 MSAC meeting and decided to cease interim funding, effective 1 November 2012.

Following initial contact in May, on 29 June 2012, representatives of HBOT providers met with Departmental officers to discuss concerns with the decision and to advise on the existence of relevant new information for MSAC. This related to the collection of new data of higher quality evidence than previously available which, when completed, was felt would address the committee's information requirements. Arrangements were agreed to facilitate an urgent referral to MSAC.

On 16 July 2012, an application was lodged with the new information and a summary of the concerns with the previous advice was received.

On 2 August 2012, MSAC considered the application, decided that the new information was insufficient to change its previous advice and reaffirmed the basis of its previous advice.

8. Recent Reconsideration

In seeking a review of the MSAC decision, the HBOT applicants have apparently disregarded the MSAC Public Summary Document for 1054.1 and continued to contest the Assessment Report. As the Public Summary Document indicates, MSAC considered (and in August reconsidered) a broad range of information including the Assessment Report, the dissenting report and other material. In the Public Summary Document, MSAC highlighted some of its concerns with aspects of the Assessment Report and the committee reached its own conclusions.

The key issues in this area are that the evidence for HBOT doesn't show sustained effectiveness at this time. MSAC reaffirmed its primary reliance on the randomised sham-controlled trial in chronic non-diabetic leg ulcers not responding to other treatment for at least two months published by Hammarlund and Sundberg in 1994 as its basis for determining the comparative effectiveness of adding HBOT to ongoing conventional therapies. This study did not show a statistically significant difference between the results from HBOT and placebo after 18 weeks.

The multicentre prospective ANZHMG Wound Care study does not change the comparative effectiveness conclusions because it provides a much less confident basis for making a comparative assessment. Additionally, MSAC had concerns about the voluntary registration of participants rather than consecutive recruitment and its less complete reporting of outcomes for participants who did not subsequently receive HBOT.

At this stage, the proponents of HBOT are unable to demonstrate that HBOT is clinically effective and this is the basis of MSAC's recommendation to Government that interim

funding should cease. Since the first MSAC assessment in 2000, the reliance of the assessment on the Hammarlund and Sundberg study has been known and the applicants have had more than a decade to conduct a randomised trial that could demonstrate long-term effectiveness. This has not been done. Over that period, the treatment of non-diabetic chronic wounds by HBOT has drawn more than $11 million of MBS funding.

The notion that it is now appropriate to continue interim funding for this indication for a further indeterminate period was not supported by MSAC. MSAC noted that the update given as part of the August 2012 submission highlighted recruitment difficulties and indicated that the proposed three-year timeframe was unlikely to be met. Effectively, the applicants are seeking to extend the period of interim funding to more than fifteen years on the basis of evidence that was first assessed as being insufficient to justify funding in 2000.

MSAC's advice to the Minister

After re-considering the strength of the available evidence in relation to the safety, clinical effectiveness and cost-effectiveness of hyperbaric oxygen therapy (HBOT) for chronic non-diabetic wounds, MSAC reaffirmed its November 2011 advice to the Minister that it does not support public funding for this indication on the basis of insufficient evidence that it is more effective and acceptably cost-effective compared with usual care without HBOT.

9. Subsequent Activity

Following the outcome of the August consideration by MSAC, the applicants were offered the opportunity to highlight any errors of fact that they believed were present in the MSAC analysis.

Meetings were held with Hyperbaric Health and other interested parties on 5, 10 and 13 September. Dr Hawkins of Hyperbaric Health made a submission on 17 September which outlined the concerns of the affected parties. These continued to focus on the Assessment Report, rather than the MSAC documents. The material, together with the various MSAC documents was forwarded to NHMRC with a request to review the material and provide advice about the approach and the issues raised.

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. Further, NHRMC noted that the evidence presented to MSAC was not particularly strong, with the RCT being small (16 patients only). The applicants and Hyperbaric Health were contacted on 12 October and this information was passed to them.

There have been a number of subsequent discussions and correspondence with the applicants, most recently with a request on 29 October that "MSAC review itself again in the light of new information". The HBOT applicants remained dissatisfied with the decision to discontinue Medicare funding from 1 November 2012.

10. Conclusion

MSAC has considered HBOT on four occasions since 2000 and on each occasion that it considered the evidence it has had input from the HBOT industry, including HBOT clinicians. Following the publication of the Public Summary Document for Application 1054.1, the applicants have been afforded a number of opportunities to remake the case for public funding. The cessation of Medicare funding is a reasonable outcome of a process that has found that there is no conclusive evidence that HBOT for the treatment of chronic non-diabetic wounds is any more effective than conventional therapy alone. Additionally, while the applicants have commenced recruitment for a trial, there does not appear to be any reasonable prospect of better evidence arising until the trial is complete, which may take some years.

The decision by government to discontinue Medicare funding is consistent with the government's commitment to evidence-based decision making. It is also consistent with the approach taken with another interim-funded item, vertebroplasty (Application 27.1) where the randomised control trial evidence indicated that the treatment was not clinically effective and interim funding was discontinued.

It is also important to note that Medicare funding continues for HBOT for a range of conditions where the scientific evidence has demonstrated beneficial outcomes for patients, and that other alternative funding for conventional treatment of chronic wounds remains available. HBOT remains funded through the MBS for other indications – diabetic wounds including diabetic gangrene and diabetic foot ulcers, soft tissue radionecrosis, osteoradionecrosis, necrotising soft tissue infections including necrotising fasciitis or Fournier's gangrene, air or gas embolism, gas gangrene, and decompression illness.

ATTACHMENT 1:

CHRONOLOGY OF MSAC CONSIDERATIONS

April 1998 - MSAC established by Minister Wooldridge
First Formal Consideration of HBOT by MSAC – 2000
MSAC ID 1018-1020
Date 16 August 2000
MSAC Chair Stephen Blamey
MSAC Advice:
The MSAC recommended that **public funding should be supported** for HBOT administered in either a multiplace or monoplace chamber, as appropriate, for the following indications:

- decompression illness, gas gangrene, air or gas embolism. HBOT is widely accepted as standard clinical care in the management of these life-threatening conditions for which there are limited alternative treatment options;
- diabetic wounds including diabetic gangrene and diabetic foot ulcers. There is evidence that HBOT is effective in promoting wound healing, and reducing the length of hospital stays and the likelihood of major amputations in patients with diabetic wounds. There may also be cost savings associated with these treatment benefits; and,
- necrotising soft tissue infections including necrotising fasciitis and Fournier's gangrene and the prevention and treatment of osteoradionecrosis. These are serious conditions in which HBOT provides a non-invasive treatment option which may have a beneficial effect and offer cost-savings. Further studies are required to provide more conclusive evidence of an effect but are difficult to undertake due to the ethical and practical constraints of conducting trails in these conditions.
- **Public funding should be continued** for HBOT use in these conditions until conclusive evidence becomes available that indicates it is not effective or that other treatments are preferable and more cost-effective.
- Since there is currently insufficient evidence pertaining to HBOT use in the following indications, the MSAC recommended that **public funding should not be supported** for HBOT administered in either a multiplace or monoplace chamber, for:
  thermal burns, non-diabetic wounds and decubitus (or pressure) ulcers, necrotising arachnidism, actinomycosis, soft tissue radionecrosis, osteomyelitis, skin graft survival, multiple sclerosis and cerebral palsy, cardiovascular conditions including acute myocardial infarctions, cerebrovascular disease, and peripheral obstructive arterial disease, soft tissue injuries including acute ankle sprains and crush injuries, facial paralysis (Bell's palsy), cluster and migraine headaches, Legg-Calves-Perthes disease, sudden deafness and acoustic trauma, Crohn's disease, osteoporosis, cancer, carbon monoxide poisoning, cyanide poisoning, head trauma, cerebral oedema, acquired brain injury, cognitive impairment, senile dementia, glaucoma, keratoendotheliosis, HIV infection, anaemia from exceptional blood loss, insulin-dependent diabetes mellitus, facial neuritis, arthritis, spinal injuries and non-union of fractures.

The MSAC has not considered safety standards for HBOT services administered in either multiplace or monoplace chambers, in detail, but endorses a standard for facilities, staffing and training which meets that in development by Standards Australia
Government Decision: Endorsed by the Minister for Health and Aged Care 9 February 2001

Second Formal Consideration of HBOT by MSAC – 2003

MSAC ID: 1054
Dates: 21 May 2003 and 19 November 2003
MSAC Chair: Stephen Blamey
MSAC Advice:
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.
Government Decision: Endorsed by the Minister for Health and Ageing 31 August 2004

Third Formal Consideration of HBOT by MSAC – 2011

MSAC ID: 1054.1
Date: 29 November 2011
MSAC Chair: Robyn Ward
MSAC Advice:
After considering the strength of the available evidence in relation to the safety, effectiveness and cost-effectiveness of Hyperbaric Oxygen Therapy for the treatment of localised non-neurological soft tissue radiation injuries (that have not responded to usual treatments), excluding lymphoedema following breast cancer, MSAC **supports** continued public funding for HBOT for this indication.

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
Government Decision: The Minister noted MSAC's advice 30 April 2012.

Fourth Consideration of HBOT by MSAC – 2012

MSAC ID: 1054.1
Date: 2 August 2012
MSAC Chair: Robyn Ward
MSAC Advice:
After re-considering the strength of the available evidence in relation to the safety, clinical effectiveness and cost-effectiveness of hyperbaric oxygen therapy (HBOT) for chronic non-diabetic wounds, MSAC reaffirmed its November 2011 advice to the Minister that it does not support public funding for this indication on the basis of insufficient evidence that it is more effective and acceptably cost-effective compared with usual care without HBOT. In relation to the indication of HBOT for radiation soft tissue injury, MSAC advised the following text for the MBS item descriptor:

HYPERBARIC OXYGEN THERAPY, for treatment of localised non-neurological soft tissue radiation injuries (excluding radiation-induced soft tissue lymphoedema of the arm after treatment for breast cancer) performed in a comprehensive hyperbaric medicine facility, under the supervision of a medical practitioner qualified in hyperbaric medicine, for a period in the hyperbaric chamber of between 1 hour 30 minutes and 3 hours, including any associated attendance.

Government Decision: Implement 1 November 2012.

ATTACHMENT 2:
PUBLIC SUMMARY DOCUMENT FROM NOVEMBER 2011 MSAC CONSIDERATION

http://www.msac.gov.au/internet/msac/publishing.nsf/Content/2530500FB68F3776CA2576D500110722/$File/MSAC_1054.1_%20PSD.pdf

ATTACHMENT 3:

SUMMARY OF MSAC'S AUGUST 2012 CONSIDERATION AND RATIONALE FOR ADVICE

http://www.msac.gov.au/internet/msac/publishing.nsf/Content/2530500FB68F3776CA2576D500110722/$File/MSAC-56th-ShortMinutes-1054.1-HBOT.pdf