

<b>Title:</b>	<b>LeukoScan<sup>®</sup> for use in diagnostic imaging of the long bones and feet in patients with suspected osteomyelitis, including those with diabetic foot ulcers</b>
<b>Agency:</b>	Medical Services Advisory Committee (MSAC) Commonwealth Department of Health and Ageing GPO Box 9848, Canberra ACT 2601, Australia
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## **Aim**

To assess the safety, effectiveness and cost-effectiveness of LeukoScan<sup>®</sup> for use in diagnostic imaging of the long bones and feet in patients with suspected osteomyelitis, including those with diabetic foot ulcers, relative to comparator diagnostic radiopharmaceuticals ie, technetium-99m stannous colloid labelled white blood cell (WBC) scanning or gallium-67 scanning.

## **Conclusions and results**

### **Safety**

The available published and unpublished data suggest that the level of adverse events and the probability of inducing a human anti-mouse antibody (HAMA) response following LeukoScan<sup>®</sup> administration are both low. LeukoScan<sup>®</sup> offers a safety advantage over technetium-99m stannous colloid labelled WBC scanning with reduced preparation requirements and no need for blood handling. It also offers a safety advantage over gallium-67 scanning through reduced exposure to ionising radiation. In both cases, the safety advantage appears to be marginal.

### **Effectiveness**

There are no head-to-head studies of LeukoScan<sup>®</sup> and the main technologies that it might replace in Australia (ie, technetium-99m stannous colloid labelled WBC scanning or gallium-67 scanning). Therefore, an analysis was undertaken of trials reporting a direct comparison of the diagnostic accuracy of LeukoScan<sup>®</sup> with indium-111 and technetium-99m labelled hexamethylpropyleneamine oxime (HMPAO) WBC scanning (diagnostic modalities in common usage internationally). The diagnostic accuracy of LeukoScan<sup>®</sup> was not significantly different from indium-111 or technetium-99m labelled HMPAO WBC scanning in patients with diabetic foot ulcers nor in those with suspected osteomyelitis of the long bones.

### **Cost-effectiveness**

An economic analysis was conducted to explore the cost-effectiveness of LeukoScan<sup>®</sup> based on the marginally better accuracy of LeukoScan<sup>®</sup> when compared with indium-111 and technetium-99m labelled HMPAO WBC scanning. These analyses indicate that the incremental cost of LeukoScan<sup>®</sup> per additional patient free of osteomyelitis in long bones and for patients free of osteomyelitis secondary to diabetic foot ulcer is \$24,056 and \$26,348, respectively. In both cases the incremental cost of LeukoScan<sup>®</sup> per additional patient free of osteomyelitis is greater than the cost of treating a patient with osteomyelitis.

## **Recommendation**

LeukoScan<sup>®</sup> is safe and as effective as current methods of WBC scanning, but is more costly. MSAC recommends that additional funding is justified for patients who do not have access to ex-vivo WBC scanning.

## **Methods**

MSAC conducted a systematic review of the medical literature pertaining to LeukoScan<sup>®</sup> and comparator diagnostic radiopharmaceuticals including technetium-99m stannous colloid labelled WBC scanning and gallium-67 scanning. In addition, a search of studies of LeukoScan<sup>®</sup> with indium-111 and technetium-99m labelled HMPAO WBC scanning was conducted in order to assess diagnostic accuracy. A thorough search of the medical literature was carried out via electronic databases and health technology websites. Those citations that met predefined inclusion criteria were included in the review of evidence.