**Title: LeukoScan® for use in diagnostic imaging of the long bones and feet in patients with suspected osteomyelitis, including those with diabetic foot ulcers**

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# Aim

To assess the safety, effectiveness and cost-effectiveness of LeukoScan® 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The available published and unpublished data suggest that the level of adverse events and the probability of inducing a human anti-mouse antibody (HAMA) response following LeukoScan® administration are both low. LeukoScan®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®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® with indium-111 and technetium-99m labelled hexamethylpropyleneamine oxime (HMPAO) WBC scanning (diagnostic modalities in common usage internationally). The diagnostic accuracy of

LeukoScan® 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®based on the marginally better accuracy of LeukoScan® when compared with indium-111 and technetium-99m labelled

HMPAO WBC scanning. These analyses indicate that the incremental cost of LeukoScan®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® per additional

patient free of osteomyelitis is greater than the cost of treating a patient with osteomyelitis.

# Recommendation

LeukoScan® 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® and comparator diagnostic radiopharmaceuticals including technetium-99m stannous colloid labelled WBC scanning and

gallium-67 scanning. In addition, a search of studies of LeukoScan® 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.