



Australian Government
Department of Health and Ageing

PRIVATE HEALTH INSURANCE CIRCULAR

Medical Benefits Division
Private Health Insurance Branch
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PHI 53/12
25 July 2012

PROSTHESES LIST CLINICAL EVIDENCE REQUIREMENTS

Purpose

The purpose of this circular is to publish the finalised “Evidence Requirements for Assessment of Applications for the Protheses List” (the *Clinical Evidence Requirements*).

Background

The Protheses List Advisory Committee (PLAC) developed this document to provide a framework to help refine and clarify minimum requirements to apply to evidence that is used to support applications to list devices on the Protheses List.

It provides a consistent set of principles that will be used to guide the Clinical Advisory Groups (CAGs), Panel of Clinical Experts (PoCE) and PLAC in their evaluation of applications to list prostheses, and sponsors in preparing their applications.

It is not a set of rules for clinical evidence, but rather provides guidance on the types and levels of evidence that would be expected to support applications.

The CAGs and PoCE will interpret the principles in the context of their specialties. They may provide further guidance on evidence requirements for sub-sets of products if needed.

What next?

The PLAC will formally review the Clinical Evidence Requirements document in June 2013, and in the meantime would welcome ongoing feedback from users of the document about its usefulness and effectiveness.

The PLAC is also progressing work on developing guiding principles on the consideration of the health economics aspects of applications to list prostheses on the Protheses List.

If you require further information, please telephone: (02) 6289 9853/24 hr answering machine or email the enquiry to PrivateHealth@health.gov.au
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