PROSTHESES LIST
CLINICAL EVIDENCE REQUIREMENTS

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

Background
The Prostheses 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 Prostheses 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 Prostheses List.