

## **Two year clinical evidence requirements**

Following discussions between the PLAC Chair, the Department and the MTAA, it has been agreed that two years of follow-up clinical data to enable the approval of some prostheses will no longer be required as a matter of course for Prostheses List applications making claims of non-inferiority against a comparator in an existing group or subgroup where the same or a lower benefit is sought. Where an application claims a device is comparable to a listed device and a cost effective benefit has been set already, data required will need to demonstrate non-inferiority.

For devices claimed to be clinically superior, or for entirely new technology, the sponsor of the product will need to provide data to demonstrate the clinical benefits of the new device compared with other listed devices and/or treatment options and to justify estimation of a benefit increase or an initial benefit. It is difficult to give details for every possible option here. New classes of device will often require a full Health Technology Assessment (HTA) process to estimate a cost-effective benefit. Where a full HTA is required, the sponsor will be asked to make a submission to the Medical Services Advisory Committee.

The requirement for two years of follow-up clinical data (referred to as the 'two year rule') has historically been applied to some devices. As a consequence, applications for inclusion on the Prostheses List for some prostheses have been rejected due to not meeting the 'two year rule' requirements.

### **Information for sponsors:**

For a new application:

- If you are intending to submit an application on the basis of non-inferiority and include the prosthesis in an existing group, you are no longer required to submit two year follow-up clinical data. However, you need to ensure that you have submitted sufficient evidence to support non-inferiority against the comparator.

For applications currently being assessed:

- All applications under assessment for the August 2018 PLAC and onwards will be assessed as outlined above for new applications.

For previously rejected or applications previously deferred :

- These applications will need to be re-submitted for consideration under the revised assessment arrangements.

The MTAA and the Department will work together with other stakeholders to revise the application documentation to facilitate the implementation of these changes. However, while this work is undertaken, this should not prevent companies to continue to submit applications for Prostheses Listing.

Interested parties will have an opportunity to contribute to the development of guidance for applicants as part of the work of the [Industry Working Group on Quality of Information and Guidance](#).