



Australian Government
Department of Health and Ageing

PRIVATE HEALTH INSURANCE CIRCULAR

Medical Benefits Division
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PROSTHESES LIST HEALTH TECHNOLOGY ASSESMENT GROUPING REVIEW – SOCAG PHASE 3 & DEFINITION FOR BIOLOGICALLY ACTIVE

Purpose

The purpose of this circular is to advise that the finalisation of the HTA Review of Phase 3 Specialist Orthopaedic Clinical Advisory Group (SOCAG) products has been deferred and that a definition for 'Biologically Active' has been approved.

HTA Grouping Review – SOCAG Phase 3

The proposed changes to the grouping scheme and group benefits for products covered by Phase 3 of the HTA Review of SOCAG products has been deferred. This decision was made by the PLAC to allow further review of the groups and group benefits and further consultation with sponsors. It is expected that this final part of the HTA Review will be completed for the February 2013 Prostheses List.

Definition for Biologically Active

The PLAC has endorsed a definition for 'Biologically Active', to assist with the grouping of products in the following four Bone Graft Substitute groupings:

- 6.3.15.13 Biologically Active Bone Inductor, 0 – 2.5mg
- 6.3.15.14 Biologically Active Bone Inductor, >2.5mg – 5mg
- 6.3.15.15 Biologically Active Bone Inductor, >5mg – 10mg
- 6.3.15.16 Biologically Active Bone Inductor, >10mg

The definition of Biologically Active is '*A molecule or protein that actively and directly initiates and promotes osteogenesis in a heterotopic site.*'

Sponsors requesting the grouping of product(s) in any of these four groupings should include evidence with their applications to demonstrate that the product(s) meet(s) the above definition. Sponsors with pending applications for products to be grouped as Biologically Active, should have already been contacted by the Department.

The field of medical devices is an evolving one and from time to time the PLAC will need to create, review and/or update definitions to ensure that they remain contemporary and that

they assist stakeholders in the correct grouping of products on the Prostheses List. For very specialised categories of devices, the PLAC will sometimes request expert external advice to assist it and the relevant Clinical Advisory Groups and the Panel of Clinical Experts Two external experts were engaged to assist the SOCAG and the PLAC to develop the above definition for Biologically Active and this approach will be used in future as the need arises.

If you require further information, please telephone: (02) 6289 9853/24 hr answering machine or email the enquiry to PrivateHealth@health.gov.au
Internet: <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-phicirculars2012-index1>
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