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PROSTHESES LIST – LISTING OF CERTAIN TEXTURED BREAST IMPLANTS

The purpose of this circular is to inform stakeholders about action being taken that might impact on the listing of and/or benefits payable for certain textured breast implants on the Prosthesis List.

Following the [TGA's public statement](#) on its review of textured breast implants, the delegate of the Minister for Health has written to sponsors of devices identified by the TGA and listed on the Prosthesis List, advising that proposed action is being considered to revoke the granting of the applications to list the devices.

The TGA statement indicates that the TGA is considering cancelling or suspending the Australian Register of Therapeutic Goods (ARTG) entries for certain textured breast implants as part of its ongoing work regarding breast implant associated anaplastic large cell lymphoma (BIA-ALCL).

Criterion 1 for listing on the Prosthesis List is that the product must be entered and current on the ARTG. If the TGA cancels or suspends the ARTG entry of a textured breast implant, the usual practice is to remove it from the Prosthesis List. Sponsors of these devices have been invited to make submissions on why they should remain on the Prosthesis List.

Another criterion for listing – Criterion 5 is:

The product has been compared to alternative products on the Prosthesis List or alternative treatments and

- (i) assessed as being, at least, non-inferior in terms of clinical effectiveness; and*
- (ii) the cost of the product is relative to its clinical effectiveness.*

Based on the TGA statement, it is appropriate to revisit the clinical effectiveness and costs of the identified textured breast implants compared to smooth breast implants on the Prosthesis List.

Sponsors have been invited to make submissions on how, based on currently available information, the identified products compare with smooth breast implants. Any submissions made will be put to the Prosthesis List Advisory Committee and claims for continued Prosthesis List benefits arising from those submissions will be put to the Medical Services Advisory Committee.

Submissions in relation to continued listing on the Prosthesis List following ARTG cancellation or suspension are to be made to the Department by close of business on **29 July 2019**.

Submissions in relation to Criterion 5 – comparative clinical effectiveness are to be made to the Department by close of business on **26 August 2019**.

The Department will inform stakeholders of any resulting changes to the Prosthesis List before they take effect.