02 March 2021
Coronavirus (COVID-19) health alert

Australian Government
Department of Health

PHI 89/20 Removal of Urogynaecological Mesh Devices

This circular provides information for stakeholders on the implications for the Prostheses List of the reclassification of urogynaecological mesh devices to high-risk in Australia.

Date published:
21 December 2020

Type:
PHI circular

PHI circular type:
Prostheses announcement

Intended audience:
Health sector

In accordance with Therapeutic Goods (Medical Devices) Regulations 2002, urogynaecological mesh devices have been reclassified to Class III. Further information on the reclassification and the urogynaecological mesh devices approved under the new regulatory requirements is available on the Therapeutic Goods Administration (TGA) website.

Sponsors of some urogynaecological meshes did not reclassify their devices by the required date of 1 December 2020, and requested cancellation of their respective entries from the Australian Register of Therapeutic Goods (ARTG).

One of the criteria for listing the product on the Prostheses List is that the product must be entered and current on the ARTG. The billing codes where the entry is suspended or cancelled from the ARTG will be removed from the Prostheses List.

The removal of the billing code may be achieved through an amendment to Schedule of the Private Health Insurance (Prostheses) Rules under section 333-20 of the Private Health Insurance Act 2007.

The urogynaecological meshes that are no longer on the ARTG, and respectively will be removed from the Prostheses List are listed in the table on page 2.

The Rules take effect on the day they are registered on the Federal Register of Legislation. It is anticipated the Amendment Rules will be made and registered in early January 2021.

Further information – future listings

Any sponsor with a Class III ARTG inclusion for their urogynaecological mesh devices will be able to submit a new Prostheses List application for their device(s).

Any queries in relation to the Prostheses List should be sent to prostheses@health.gov.au.

PL Billing Code	Product Name	Description	Product Sub Group	ARTG	ARTG status
CT013	Aris Transobturator Sling System	Sling System for female stress urinary incontinence	05.01.03.02 - Female	157074 160738	Cancelled
CT021	Supris Retropubic Sling	Supris Retropubic Sling System for female urinary incontinence		160738	Cancelled
CT016	Restorelle M Smartmesh	Smartmesh, Type 1, macroporous, soft, knitted, monofilament polypropylene mesh.	05.04.01.01 - <500 sq cm	190172	Cancelled
CT017	Restorelle Y Smartmesh	Smartmesh for vaginal vault prolapse repair for abdominal, laproscopic or robotic sacrocolpopexy.			
CT019	Restorelle L Smartmesh	Smartmesh, Type 1, macroprous, soft, knitted, monofilament polypropylene mesh			
CT020	Restorelle XL Smartmesh	Smartmesh, Type 1, macroporous, soft, knitted, monofilament polypropylene mesh	05.04.01.02 - ≥500 sq cm		
BS078	Advantage, Advantage Blue	Transvaginal Mid-Urethral Sling System	05.01.03.02 - Female	104326	Cancelled
BS096	Lynx, Lynx Blue	Suprapubic Mid-Urethral Sling System			
BS097	Obtryx Transoburator Mid-Urethral Sling System	Polypropylene mesh sling			
BS140	Advantage Fit, Advantage Fit Blue	Transvaginal Mid-Urethral Sling System			
BS226	Obtryx II Transobturator Mid-Urethral Sling System	Polypropylene mesh sling			
BS252	Upsylon Y-Mesh Kit	Y-Mesh with single use instrument for mesh placement	05.04.01.01 - <500 sq cm	150342	Cancelled

Tags:

Private health insurance