Office of Health Technology Assessment Technology Assessment and Access Division MDP 951 GPO Box 9848 CANBERRA ACT 2601

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PROSTHESES LIST – REMOVAL OF MACRO TEXTURED BREAST IMPLANTS AND TISSUE EXPANDERS

The delegate for the Minister for Health has made the Private Health Insurance (Prostheses) Amendment Rules (No. 5) 2019 to remove the listings of five macro textured breast implants and tissue expanders from the Prostheses List.

This follows action taken by the sponsor, Allergan Australia Pty Limited, to voluntarily recall these devices commencing from 30 July 2019.

The listings removed from the Prostheses List are:

Billing Code	Sponsor	Product Name	Description	Size	Benefit	ARTG
AW004	Allergan Australia Pty Limited	Natrelle® 510 TruForm™ Dual Gel Breast Prosthesis	Anatomical textured implant with dual gel for projection of nipple/areola complex, concave base and tapered edges for minimisation of edge/thoracic wall palpability.	LX sizes from 130- 575 grams, MX sizes from 145-600 grams, FX sizes from 165-630 grams	\$1,170	171387
AW005	Allergan Australia Pty Limited	Natrelle® INSPIRA® TruForm Textured Mammary Implant	Round implants with textured surface. Available in four projections: low, moderate, full and extra-full; and two cohesive gel types: TruForm™ 1 Responsive Gel and TruForm™ 2 Soft-Touch™ Gel.	110 - 800 grams	\$741	175422 175425
AW007	Allergan Australia Pty Limited	Natrelle® 410 BioDIMENSIONAL™	TruForm™ 2 Soft-Touch™ Gel and TruForm™ 3 Cohesive Gel Textured Mammary Implants. Full, moderate or low height; Extra full,full, moderate or low projection	125 - 775 grams	\$1,170	171475 171512
AW012	Allergan Australia Pty Limited	Natrelle® 150, 1- Stage BioDimensional™ Tissue Expander	Full height, Short Height, textured	9.6 -16cm width x 8 - 17cm height x 4.2 - 7.1cm projection	\$1,989	169956
AW013	Allergan Australia Pty Limited	Natrelle® 133, 2- Stage BioDimensional™ Tissue Expander	Silicone Elastomer. Saline filled.	150-950 cm3	\$1,024	175797

The Amending Rules commences the day after registration.