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By Email Only

Date:	08/10/2019
To:	All General Practitioners
Cc:	ICGP
From:	Dr Vida Hamilton, NCAGL, Acute Operations
RE:	BIA ALCL – Primary Care Advisory
Reference:	2019 NCCN Consensus Guidelines on the Diagnosis and Treatment of Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) *Clemens et al. Aesthet Surg J. 2019 Jan 31;39(Supplement_1):S3-S13. doi: 10.1093/asj/sjy331.*

Dear Colleague,

Following on from the HPRA advisory earlier this year relating to Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL), a rare malignant complication of breast implants, I would like to update you on the current understanding of the disease risks. The Allergan BIOCELL textured-surface implants have been most commonly associated with this disease and the risk associated with these implants is now estimated at 1:3300 (Magnusson et al. Plast Reconstr Surg. 2019 May;143(5):1285-1292). These particular implants have been withdrawn from use in Europe since December 2018 and are now subject to a global withdrawal by the company. Whilst this disease has been described in other less textured implants the risk appears considerably less. No cases have been reported to date with exposure only to smooth implants.

In view of this, the HSE and NCCP are preparing to inform individuals with implants of this condition. The advisory will reassure asymptomatic patients that they do not need to do anything. There is no recommendation nationally or internationally to have implants removed. Patients will be informed that the disease is rare, and advised to contact the hospital only in the setting of a new implant related symptom or if they require clarification on the content of the advisory. As this is a low risk issue, individuals who are still in a 5-year

follow-up programme with their surgeon will have this issue discussed with them at their next routine appointment. The Cancer Hospitals will via a dedicated telephone line receive queries and provide reassurance to individuals with concerns and, where appropriate, organise clinical review with the appropriate breast/ plastic surgeon. Patients are asked to be breast aware and should they develop symptoms or signs of breast disease to seek medical review.

Individuals who have received implants in the private sector will be contacted by their implant surgeon and followed up with them as appropriate. However, there is a third group of individuals who received their implants abroad or by providers who are no longer in operation in Ireland. These individuals will be informed by the public awareness campaign supported by the HSE, HPRA and IAPS websites.

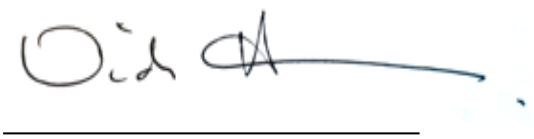
The disease typically presents 7-10 years post operatively (range 1 to 40 years) with a peri-implant effusion, or more rarely a peri-implant mass with or without axillary adenopathy. The effusion is typically rapidly developing and unilateral, although cases of bilateral disease have been described, and because of this is usually picked up at the 'seroma' stage and curative treatment is by local en-bloc excision with no adjuvant therapy required. Occasionally with late presentation adjuvant therapy is required but even in these cases treatment outcomes are good. Overall 5-year survival is more than 90%.

You may be consulted for reassurance or by patients who have found an abnormality on self-examination. Given the rare nature of this disease abnormality is more likely to be due to benign complications of breast implants such as contractures or indeed breast cancer which is much more common than BIA-ALCL. If you are concerned about an abnormality on examination you should refer your patient to the symptomatic breast clinic, marking the referral as urgent and documenting the presence of the implant. If however, there are no obvious concerning clinical findings and the patient requests a further clinical review, where appropriate, onward referral for breast/ plastic surgeon consultation at the local cancer hospital or by their implanting surgeon should be made.

Concerned individuals who have had their implants overseas or by another provider should make every effort to find out from the implanting hospital or provider which type of implant they have received as there is no way to ascertain the type by examination or imaging and the type clearly has an impact on the risk. I have attached the HPRA advisory for further information.

Thank you for your ongoing work and care for the population.

Regards



Dr. Vida Hamilton

National Clinical Advisor and Group Lead – Acute Operations