

# Referral Guidelines: Review of patients with breast implants related to concerns of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL)

***Referrals for patients deemed not to meet the clinical indications for referral will be returned to the referrer for clinical review.***

## Guidance for GPs- Summary

There is an association between some breast implants and the risk of breast implant associated anaplastic large cell lymphoma (BIA-ALCL). In response to this, in early 2020, the WA Department of Health is sending letters to all patients who have had implants in the last 15 years in a WA public hospital.

Patients with symptoms of BIA-ALCL are being advised to seek a review by their GP if they have concerns regarding their implant or symptoms such as swelling, pain, a rash or a lump in their breast, armpit and elsewhere, or if they are not sure about changes in their breasts.

Patients with a seroma or other clinical signs and symptoms of BIA-ALCL are required to have a bilateral diagnostic breast ultrasound scan prior to referral to a specialist.

If you do not have any clinical concerns, referral of the patient for specialist review may not be warranted and it is recommended that you arrange a follow-up review with the patient at a later date. Ultrasound is not recommended for asymptomatic patients unless there are clinical concerns.

There is information below on how to make a referral for symptomatic patients who have had implants in the public health system. Private patients should be referred to their implanting surgeon or private hospital for further advice if necessary.

Specialist opinions can be sought from the relevant hospital clinic if there are any significant clinical or radiological concerns.

Further information on BIA-ALCL can be found at the Therapeutics Goods Administration (TGA) breast implant hub <https://www.tga.gov.au/hubs/breast-implants>.

## Background

There is an association between some breast implants and the risk of anaplastic large cell lymphoma, a rare form of non-Hodgkin lymphoma. The Therapeutic Goods Administration (TGA) continues to review and assess breast implants available in the Australian market. For more information and the latest updates on breast implants, including recalls, see the TGA's Information for Health Professionals. <https://www.tga.gov.au/breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl>.

The TGA advises that implants with a higher surface area and surface roughness (textured or polyurethane implants) are associated with a significantly higher risk of developing BIA-ALCL. For the latest data on BIA-ALCL cases in Australia go to the [TGA breast implant hub](#).

These *Referral Guidelines* have been developed to assist GPs in identifying patients with clinical indications for BIA-ALCL and to define the access criteria for public hospital breast implant review.

To ensure patients access timely care and appropriate management, referrals to review breast implants sent to the Department of Health's Central Referral Service (CRS) for specialist outpatient services for patients (over 16 years of age) will be assessed using the referral criteria outlined below. Only referrals requiring specialist level care will be accepted.

These criteria for review of breast implants are in place from 20 January 2020.

## Who needs referral?

The TGA advises that BIA-ALCL usually presents as enlargement of the breast due to a spontaneous late seroma. Less commonly, symptoms may include pain, a rash on the breast, a lump in the breast, or lymphadenopathy.

Patients with symptoms of BIA-ALCL, or those who are unsure about changes in their breast, should be reviewed by a GP and symptomatic patients should have a bilateral diagnostic breast ultra sound scan undertaken prior to referral to a specialist. Please note that the TGA advises that there does not appear to be a role for mammography in the detection or investigation of BIA-ALCL.

The TGA does not recommend the removal of breast implants from asymptomatic patients due to the risks associated with an anaesthetic and surgery.

## For urgent referrals – patients requiring review within 7 days

The TGA advises that it is important that all patients with suspected seroma are reviewed as soon as possible by their implanting surgeon. Patients with a large seroma or clinical signs and symptoms of BIA-ALCL confirmed by pre-referral ultrasound need urgent assessment.

The CRS does not accept or process referrals for patients who require immediate review (within the next 7 days).

Immediate referrals (requiring review within 7 days) need to be sent directly to the hospital following a discussion with the relevant hospital clinician. Contact phone numbers are provided below. Please contact the hospital via the switchboard and request to speak to the Clinical Nurse Specialist or the Breast Fellow for each unit:

- Fiona Stanley Hospital – phone (08) 6152 2222 (also for Peel patients)
- Royal Perth Hospital – phone (08) 9224 2244
- Sir Charles Gairdner Hospital – phone (08) 6457 3333

## Non-urgent referrals from General Practitioners

Non-urgent referrals are for patients with symptoms (this includes patients who currently have implants and those who have had their implants removed) which may include enlargement of the breast, swelling, pain, rash on the breast, lump in the breast, armpit or elsewhere, lymphadenopathy or other changes in the breast. **Symptomatic patients should have a bilateral diagnostic breast ultrasound scan undertaken prior to referral to a specialist.**

### Triage arrangements

Referrals for patients who do not meet the criteria for an outpatient review (as determined by the triaging clinician at the hospital site) will be returned directly to the referring clinician for ongoing management in the community but may be re-referred if the condition becomes appropriate for specialist review, which is when the patient becomes symptomatic.

Referrals are triaged according to relative urgency based on:

- presenting symptoms, probable diagnosis and its potential seriousness
- how long the symptoms have been present
- severity and impact of the symptoms in the patient
- comorbidities
- findings from the diagnostic breast ultrasound.

If you are uncertain about the appropriateness of your referral, please phone the relevant hospital clinic to discuss.

### Clinic Type

- Implants placed for cosmetic reasons will be allocated to a plastics clinic.
- Implants placed as part of breast cancer surgery will be referred to breast cancer clinics.

### Ultrasound Costs

Bilateral breast ultrasound is recommended for symptomatic patients. There may be a gap payment if the Medicare rebate is less than the cost charged by the radiology provider. GPs should advise patients on their options for bulk billing and any expected out of pocket expenses.

## Referral Instructions

Referrals are to be submitted to the CRS using the Statewide standard [referral forms](#).

Please note: If the information below is not provided, the referral will be returned to the referrer for completion.

### **Checklist for referral information**

- Referral reason: Breast implant review or other
- Patient Details: As per standard CRS referral information (patient demographics, medications, allergies, etc)
- Reason for implants - reconstruction or augmentation
- Implant details (not mandatory if unable to access details)
  - Date of implantation
  - Hospital and name of implanting surgeon for most recent implant procedure
- Indication for referral – comprehensive description including:
  - Presenting symptoms, onset and duration (enlargement of the breast, swelling, pain, rash on the breast, lump in the breast, armpit or elsewhere, lymphadenopathy or other changes in the breast)
  - Evolution – progressive, stable or improving
  - Physical examination findings
- Relevant investigations- provide copies of results of relevant tests
  - Bilateral breast ultrasound for fluid collection, breast masses, and enlarged regional lymph nodes. Please note that the TGA advises that there does not appear to be a role for mammography in the detection or investigation of BIA-ALCL. Before patients are accepted for review by a tertiary hospital clinic (either plastics or breast clinic) an ultrasound examination is required for symptomatic patients. Urgent cases are exempt if discussed with the relevant hospital.

Specialist opinions can be sought from the relevant hospital clinic if there are any significant clinical or radiological concerns.

## **Asymptomatic Patients**

Where a GP does not have any clinical or radiological concerns, referral for specialist review may not be warranted. Ultrasound is not recommended for asymptomatic patients unless there are clinical concerns.

Where there is reasonable clinical uncertainty and patients do not meet the criteria for referral, it is recommended to arrange a GP review for a future date.

The NICE guidelines\* (2015) recommend that further GP review should occur if new symptoms develop, the person continues to be concerned or if their symptoms recur, persist or worsen. (\*as per the safety netting recommendations in NICE guidelines (2015)

<https://www.nice.org.uk/guidance/NG12/chapter/Recommendations-on-patient-support-safety-netting-and-the-diagnostic-process#safety-netting>

Where asymptomatic patients request further review and the GP determines that there is sufficient clinical concerns, the patient can be referred to a relevant clinic.

Information sheets on BIA-ALCL for [health professionals](#) which includes information on symptoms that would warrant referral and [TGA patient information factsheet](#) are available from the TGA website.

The TGA recommends that patients with breast implants be advised to perform breast self - examination regularly.

## Private, Overseas and Interstate Patients

[Private patients or patients who have implants overseas or interstate who want referral as a private patient](#)

Refer patients to their implanting surgeon or private hospital for further advice if necessary.

[Private patients or patients who have implants overseas or interstate who want referral as a public patient](#)

- Implants placed for cosmetic reasons will be allocated to a plastics clinic.
- Implants placed as part of breast cancer surgery will be referred to breast cancer clinics.

## Links to relevant/supporting information

For further information, please refer to:

- the TGA breast implant hub (<https://www.tga.gov.au/hubs/breast-implants>) or consumer information page (<https://www.tga.gov.au/breast-implant-associated-cancer-or-bia-alcl>),
- the TGA website (<https://www.tga.gov.au/breast-implant-associated-cancer-or-bia-alcl>), or
- the enclosed TGA Fact Sheet (also available online at <https://www.tga.gov.au/consumer-fact-sheet-recall-allergan-biocell-breast-implants>),

or contact HealthDirect on 1800 022 222 (24 hours a day, 7 days a week).