

<b>Distribution:</b>	As Appendix 1	
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<b>Category:</b>	Immediate (cascade within 6 Hours)	
<b>Title</b>	NHS Wales support for women with Poly Implant Prothese (PIP) breast implants.	
<b>What is this about:</b>	Full details are set out below.	
<b>Why has it been sent:</b>	For your information and to pass on to Colleagues	

To:  
NHS Medical Directors  
Cancer and Plastic Surgeons  
General Practitioners

Dear Colleague

## NHS Wales support for women with Poly Implant Prothèse (PIP) breast implants

### Introduction

The purpose of this communication is to make clear for patients, clinical professionals and NHS managers the proposed arrangements to assess and care for women with PIP breast implants.

This communication follows the briefing from Dr Sara Hayes, DCMO and Dr Chris Jones, Medical Director Welsh Government and NHS Wales, published on 12 January 2012 and the joint surgical statement on clinical guidance for patients, GPs and surgeons published 17 January 2012.

There is no known use of this implant by the NHS in Wales and the vast majority of these procedures have been carried out privately. The main private healthcare providers in Wales have not used these implants, but initial estimates suggest that around 500 women now resident in Wales have had implants outside of Wales.

There is no link to cancer and there is no clear evidence of an increased risk of harm compared to other brands of breast implants. Women with PIP implants do not necessarily need to have them removed.

A number of private clinics have agreed to remove implants where necessary and to replace them without cost to the patient.

NHS Wales are offering every patient treated on the NHS with PIP implants, and those originally treated privately who find their private clinic no longer exists or refuses to care for them, a consultation with a specialist plastic surgeon and a screening scan if appropriate. If, during a clinical consultation with a plastic surgeon, a decision is made to remove and/or replace PIP implants on clinical grounds, NHS Wales will fund this.

NHS Wales will require evidence that women who were originally treated privately have sought redress from their private provider, evidence that the woman is a Welsh resident and registered with a Welsh GP, and written confirmation from their implanting surgeon or clinic that they have been implanted with PIP implants and ideally details of implant type and size. We will also need to know where and when their implants were put in.

## **What is the clinical guidance?**

The advice from the NHS and plastic surgery experts is that women with PIP breast implants do not need to have them removed, unless they have symptoms such as pain and tenderness.

Routine scans are not recommended for women with PIP implants who do not have any symptoms at the moment.

A joint surgical statement on clinical guidance for patients, GPs and surgeons was published on 17 January 2012.

<http://www.rcseng.ac.uk/publications/docs/pip-statement/>

The guidance helps to explain action to be taken and the key recommendations are included below in each section related to action by patients, by GPs and by surgeons. This pathway will be reviewed and updated as necessary.

## **Action to be taken by patients**

If a patient with implants is concerned, they should:

- Find out if they have PIP implants by checking their medical notes or asking their surgeon or doctor. They can get this information free from their clinic.
- If they had the implants done on the NHS, they should speak to their surgeon or GP. Their details will be referred to the Plastic Surgery PIP Breast Implant Action Team at Morriston Hospital, Swansea.
- If they had the implants done privately they should speak to their surgeon or clinic.
- If they received their implants from a private provider and their private clinic no longer exists or refuses to support them further, they may still wish to continue to be managed privately by their clinic or by another provider.
- If they wish to access NHS care they should speak to their GP. With their GP they will need to complete a form to record the name of the clinic and details related to their PIP implant and surgery. Each patient will need to outline the actions they have taken to seek redress from their private provider. They need to return the form to the GP who will forward it to the Plastic Surgery PIP Breast Implant Action Team. The Team will write to the private clinic reminding them of their duty of care to their patient and ask what they have done to rectify the situation.
- In cases where the private provider indicates in writing that they will not provide further support to the women they have treated, the women will be offered a consultation with a specialist NHS plastic surgeon.
- If it is agreed between the patient and the surgeon that explantation is appropriate on clinical grounds, this will be arranged. If reimplantation is also clinically indicated, this will also be arranged, preferably in the same operation where possible.
- Patients who have undergone explantation following rupture/gel leak of PIP implants should be advised to attend annual follow-up for at least two years.
- Patients who underwent a 'clean' explantation or re-implantation should be advised about normal follow-up procedures.
- Where a patient decides, after consultation with specialist, not to have their PIP implants removed, they should be followed up on an annual basis. In the case of NHS patients this review would normally be carried out by the GP; private patients should be followed up by the surgeon or provider responsible for the original implantation. Patients with PIP implants should be made aware of the signs and symptoms of implant rupture and gel bleed.

### **Action to be taken by GPs**

The latest guidance advises GPs consulted by patients with PIP implants, to assess the patient for the following symptoms and signs, which may be associated with rupture/gel leak.

#### Symptoms:

- Localised pain and discomfort
- Axillary pain/discomfort
- Persistent burning sensation

#### Signs:

- Lumpiness of the breast
- Regional swelling of the lymph nodes/glands (lymphadenopathy) – this may be in the absence of other breast signs/symptoms
- Change in the shape of the breast
- Hardening or firmness of the breast
- Tenderness of the breast
- Swelling of the breast

Any women with implants who have signs in the breast or lymph nodes that would usually result in an urgent referral to a Rapid Access Breast Unit should continue to be referred in this way but all other women, including those with evidence of implant rupture should be referred to the plastic surgery breast implant action team. Note, this fast track urgent referral should only be used where there is a need to exclude serious breast disease.

#### Otherwise GPs in Wales should:

- Direct patients who received private care to contact the clinic responsible for the implants.
- Provide the attached form for patients who were originally treated privately who find their private clinic no longer exists or refuses to care for them. Completed forms should be forwarded to the Plastic Surgery PIP Breast Implant Action Team at Morriston Hospital, Swansea (see contact details below).
- Refer patients identified with PIP implants who received NHS care to the Plastic Surgery Breast Implant Action Team who are based at Morriston Hospital, Swansea. (See contact details below). This should include referral of all Welsh patients, regardless of where they live within Wales.
- The Plastic Surgery PIP Breast Implant Action Team in Swansea will make arrangements related to patients from North Wales or North Powys for assessment to be undertaken in North Wales.
- Assessment clinics will be arranged in North and South Wales by the Action Team.
- Note that there is no urgent need for treatment. Arrangements for an appointment to be assessed by a NHS plastic surgeon will be made as soon as possible.

### **Action to be taken by Health Boards**

Local Health Boards in Wales will complete a review of their surgical records to determine whether any PIP breast implants have been used in the NHS. Health Boards will notify the Plastic Surgery PIP Breast Implant Action Team in the event of identification of NHS patients with PIP implants.

## Action by surgeons

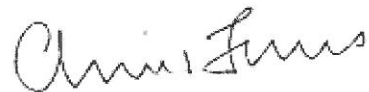
All surgeons are directed to the joint surgical statement inserted above.

**Communication address for all referrals:**

Plastic Surgery Breast Implant Action Team  
Anne Evans  
Burns and Plastic Surgery Case Officer  
Welsh Centre for Burns and Plastic Surgery  
Morrison Hospital  
Heol Maes Eglwys  
Morrison  
Swansea SA6 6AL  
Email address: anne.evans7@wales.nhs.uk  
Fax number: 01792 703875



Dr Sara Hayes  
Interim DCMO



Dr Chris Jones

Medical Director NHS  
Wales

To: NHS Wales Shared Services Partnership to forward to:

All General practitioners - please ensure this message is seen by all practice nurses and non-principals working in your practice and retain a copy in your 'locum information pack'.

All Community Pharmacists

Deputising services

HB Chief Pharmacists

HB Prescribing Advisers

Independent/Private clinics and Hospitals and Hospices throughout Wales

To: Chief Executives of Health Boards

To: Medical Directors of Health Boards **to cascade to:**  
**- Cancer and Plastic Surgeons**

To: Nurse Directors Health Boards

To: Directors of Public Health

To: Hospital Principals and Chief Pharmacists to action as per alert

cc: Public Health Wales  
Consultants in Pharmaceutical Public Health  
Chief Executives, NHS Trusts  
Principal Pharmacist Welsh Quality Control  
Principal Pharmacist Continuing Care Services  
Principal Pharmacist Welsh Medicines Information Centre  
CSSIW  
NHS Direct



GIG  
CYMRU  
NHS  
WALES

Pwyllgor Gwasanaethau Iechyd  
Arbenigol Cymru (PGIAC)  
Welsh Health Specialised  
Services Committee (WHSSC)

## NHS Wales PIP Breast Implant Data Requirements

Patients Surname	
Patients Forename	
Patients DOB:	
Patients NHS Number:	
Address	
Postcode	

GP practice	
Practice code (if known)	

Date of surgery	
NHS or Private	
Surgeon (if known)	
Provider	
Provider location	

<b>Confirmation of PIP implants</b> <i>(Please attach copy of correspondence – i.e. a detailed discharge summary)</i>	Tick as appropriate Yes(✓)
How confirmed:	
Letter from NHS provider	
Letter from private provider	
Letter from GP	
Clinic no longer exists	
<b>Implant type and size (if known)</b>	
Other breast procedure at same time? (attach discharge summary)	

<b>Confirmation of provider refusal to treat</b> <i>(Please attach copy of correspondence)</i>	
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**Communication address for data return and any queries:**

**Plastic Surgery PIP Breast Implant Action Team**

Anne Evans, Burns and Plastic Surgery Case Officer

Welsh Centre for Burns & Plastic Surgery

Morrison Hospital

Morrison

Swansea

SA6 6AL

Email address: [anne.evans7@wales.nhs.uk](mailto:anne.evans7@wales.nhs.uk)

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