Draft benefit definition: Early and locally advanced breast cancer

Contents

Disclaimer:

The breast cancer benefit definition has been developed for the majority of standard patients. These benefits may not be sufficient for outlier patients. Therefore regulation 15h may be applied for patients who are inadequately managed by the stated benefits. The procedure codes are just an indication of applicable procedure codes, however some significant procedure codes may not have been included. The benefit definition does not describe specific in-hospital management such as theatre, anaesthetists, anaesthetist drugs, supportive medication and nursing care. However, these interventions form part of care and are prescribed minimum benefits.

1. Introduction

1.1 The legislation governing the provision of the prescribed minimum benefits (PMBs) are contained in the regulations enacted under the Medical Schemes Act 131 of 1998. In respect of some of the diagnosis treatment pairs (DTPs), medical scheme beneficiaries find it difficult to know their entitlements in advance. In addition, medical schemes interpret these benefits differently, resulting in a lack of uniformity of benefit entitlements.

1.2 The benefit definition project is coordinated by the Council for Medical Schemes (CMS) and aims to define the PMB package and to guide the interpretation of the PMB provisions by relevant stakeholders. The guidelines are based on the available evidence of clinical and cost effectiveness taking into consideration affordability constraints and financial viability of medical schemes in South Africa.

2. Scope and purpose

2.1 This is a recommendation for the diagnosis, treatment and care of individuals with early and locally advanced breast cancer in any clinically appropriate setting as outlined in the Medical Schemes Act.

2.2 The purpose is to improve clarity in respect of funding decisions by medical schemes, taking into consideration evidence based medicine, affordability and in some instances cost-effectiveness

3. Epidemiology

3.1 Breast cancer is the most common cancer in women both in the developed and less developed world. In 2012, 1.7 million women were diagnosed with breast cancer while the prevalence stood at 6.3 million women. According to the World Health Organisation (WHO) Breast cancer was also the most common cause of cancer death among women with 508 000 deaths in 2011 and 522 000 deaths in 2012. Breast cancer was also the most frequently diagnosed cancer among women in 140 of 184 countries worldwide [1]

3.2 Although breast cancer is thought to be a disease of the developed world, almost 50% of breast cancer cases and 58% of deaths occur in less developed countries. Incidence rates of breast cancer vary greatly worldwide from 19.3 per 100,000 women in Eastern Africa to 89.7 per 100,000 women in Western Europe. In contrast to Eastern Africa, breast cancer was the most commonly diagnosed cancer and the leading cause of cancer death among women in Southern Africa (9000 cases, 4500 deaths)[2].

3.3 Breast cancer survival rates vary greatly worldwide, ranging from 80% or over in North America, Sweden and Japan to around 60% in middle-income countries and below 40% in low-income countries[3]. The low survival rates in less developed countries can be explained mainly by the lack of early detection programmes, resulting in a high proportion of women presenting with late-stage disease, as well as by the lack of adequate diagnosis and treatment facilities.

3.4 Currently in South Africa 10% of patients with breast cancer present with stage 1 diseases and the remainder presents with 30% each for stages two three and four[4]. According to the South African National Cancer Registry, Breast cancer was the most prevalent cancer amongst women with a lifetime risk of 1:35[5].

Table 1: Possible ICD 10 codes to identify breast cancer

ICD 10	*WHO description*	*Comments*
Z12.3	Special screening examination for neoplasm of breast	
C50.0	Malignant neoplasm, nipple and areola	
C50.1	Malignant neoplasm, central portion of breast	
C50.2	Malignant neoplasm, upper-inner quadrant of breast	
C50.3	Malignant neoplasm, lower-inner quadrant of breast	
C50.4	Malignant neoplasm, upper-outer quadrant of breast	
C50.5	Malignant neoplasm, lower-outer quadrant of breast	
C50.6	Malignant neoplasm, axillary tail of breast	
C50.8	Malignant neoplasm, overlapping lesion of breast	
C50.9	Malignant neoplasm, breast, unspecified	
D05.0	Carcinoma in situ, lobular carcinoma in situ	
D05.1	Carcinoma in situ, intraductal carcinoma in situ	
D05.7	Carcinoma in situ, other carcinoma in situ of breast	
D05.9	Carcinoma in situ, of breast, unspecified	

4. Screening

4.2 Current evidence does not support the use of mammogram for screening women below 40 years and women above 69 years[6, 7].

4.1 Screening mammogram is a PMB level of care for women between the ages of 45 to 69 years.

5. Diagnostic procedures

Women with signs and symptoms of breast cancer must undergo triple assessment for diagnosis. Triple assessment consist of clinical examination, imaging and pathological assessment [8, 9].

5.1 Clinical assessment:

5.1.1 The diagnostic work-up of early breast cancer starts with assessment of general health status which includes the complete history of the patient, family history relating to cancers, physical examination and biochemical examination.

5.1.2 Clinical examination includes bimanual palpitation of the breasts and complete examination of tall systems (bones, liver, brain and lungs) to assess distant metastases.

5.1.3 Blood tests such as liver function test, renal function tests, calcium and phosphates to assess general health and metastatic disease are PMB level of care [8].

5.2 *Imaging*

Imaging plays a crucial role for classifying and sampling both palpable and non-palpable breast abnormalities, as well as for defining the extent of breast tumours, both locally, loco-regionally, and at distant sites.

5.2.1 Diagnostic mammogram is indicated for most women with positive screening mammogram [8, 10].

5.2.2 Ultrasound is indicated for symptomatic younger women (women less than 40 years,) as they have dense breast tissue and high risk of false negatives on mammogram. Ultrasound with mammogram has a better diagnostic value as compared to either test alone in symptomatic women [11-13].

5.2.3 Magnetic resonance Imaging (MRI) of the breast is not routinely recommended. MRI is PMB level of care in cases of family history of breast cancer, women from families not tested or inconclusively tested for BRCA mutation with 20-30% lifetime risk or greater familial breast cancer associated with BRCA mutations, breast implants, lobular cancers and when the findings of conventional imaging are inconclusive [8, 14, 15].

5.2.4 Positron Emission Tomography - Computed Tomography (PET-CT) scan, three dimensional mammographic ultrasound and computed tomography scan are not PMB level of care for diagnosis[16] [8, 17]

5.3 *Pathological assessment*

5.3.1 Ultrasound guided core needle biopsy is the method of choice for diagnosing breast cancer. Core needle biopsy has been shown to reliably distinguish between in-situ and invasive cancers, allow evaluation of more histological, prognostic and predictive factors in breast cancer [18, 19].

5.3.2 Fine needle aspiration (FNA) is indicated as the first-line pathologic investigation for palpable breast lesions. In the case non-palpable lesions, suboptimal sampling and localization remains the main cause of false negative results[20]. Using ultrasound to guide FNA decreases the number of false negative results and increases the sensitivity and specificity of FNA[21, 22]

5.3.3 Excision biopsy is considered a reference standard method of evaluating a suspicious breast lesion. However, the availability of core needle biopsy has limited the role of open surgical biopsy which places the patient at risk of experiencing morbidities. A less invasive method of evaluation of breast lesions is preferred[23].

5.3.4 Frozen section biopsy is not a PMB level of care. Frozen *section biopsy* has been shown to have a limited role in the diagnosis of carcinoma and is not recommended on small lesions (< 1cm), where the pathologist believes that freezing will distort subsequent tissue morphology[23]. Current evidence discourages the use of Frozen section for evaluation of resection margins that are grossly free of tumour and on a breast excision specimen removed because of mammographic calcifications [22, 23].

5.4 Evaluation of the Axilla

5.4.1 Axillary lymph nodal status remains an important prognostic factor because treatment of breast cancer is influenced by the presence of and number of axillary lymph nodes involved.

5.4.2 Sentinel lymph biopsy is a PMB level of care for women with operable breast cancer and multicentric tumours, with ductal carcinoma in situ (DCIS) who will undergo mastectomy, who previously underwent breast and/or axillary surgery, or who received preoperative/neoadjuvant

systemic therapy are offered SLNB [24, 25]. SLNB should not be performed routinely for all patients with an initial diagnosis of DCIS [8, 15, 26].

5.5 Histological assessment

5.5.1 Progesterone receptor (PR) and HER2 status is determined on all breast cancers and breast cancer recurrences [27, 28]. Immunohistochemical staining can be performed on the core needle or excision biopsy.

6. Staging and risk assessment

The TNM classification is a universally accepted system that is used to stage breast cancer. TNM staging takes into account the size of the tumour (**T**), whether the cancer has spread to the lymph glands (lymph nodes) (**N**), and whether the tumour has spread anywhere else in the body (**M** – for metastases)[8].

6.1 Current guidelines for the management of women with early breast cancer generally recommend against the routine use of staging imaging to detect asymptomatic distant metastases at the time of diagnosis [8, 29-32].

6.2 Chest x-ray is considered for patients with clinically positive axillary nodes, large tumours, and clinical signs and/or laboratory values suggesting metastases to determine the presence of pulmonary metastases.

6.3 Bone scan is considered for patients with clinically positive axillary nodes, large tumours, clinical signs and/or laboratory values suggesting metastases, bone pain to determine the presence of metastases to bone[32]

6.4 Magnetic Resonance Imaging (MRI) is indicated in patients with clinically positive axillary nodes, large tumours, clinical signs and/or laboratory values suggesting metastases to determine metastatic regions[17]

6.5 Computed tomography (CT scan) is considered for patients with clinically positive axillary nodes, large tumours, and clinical signs laboratory values suggesting metastases to determine metastatic regions[17]

6.6 [18F]-fluorodeoxyglucose Positron emission tomography–computed tomography (FDG-PET/CT) is indicated only when conventional methods are not conclusive in determining metastases [33, 34]. According to the Radiological Society of South Africa, PET-CT scan is only indicated if:

- There is a significant chance of distal disease as determined by axillary dissection or where conventional imaging is equivocal.
- The PET-CT scan can result in up to 57% change of stage and management compared to other CI (conventional imaging).
- The PET-CT scan has a high accuracy (86% vs. 77% for CT alone) for nodal and distal metastases in patient with infiltrating ductal carcinoma.

This procedure should is not a PMB level of care unless distant metastasis is suspected with unequivocal results.

6.7 Post-operative pathological assessment is done according to the primary TNM system and maximum diameter of tumours removed, the total number of lymph nodes removed and number of positive lymph nodes and the extent of metastases in the lymph nodes. Age, tumour stage, ER expression and histological grade are used to estimate the probability of recurrence and death from breast cancer [10]

Table 2: Diagnostic work-up for breast cancer

	Procedure	**Indication**
Blood tests	Full blood count	Standard pre-operative assessment for possible bone marrow metastasis
Liver function tests	Total Bilirubin	Baseline tests to assess possible liver involvement
	Albumin	
	Alanine transminase	
	Aspartate transminase	
	Alkaline Phosphatase	
Renal function tests	Urea	Assessment of possible obstructive renal symptoms
	Creatinine	
	Electrolyte	

	Calcium	
	Phosphates	
Imaging	Mammogram	Women with positive screening mammogram
	Ultrasound	Symptomatic younger women (women less than 40 years,) as they have dense breast tissue and high risk of false negatives on mammogram.
	MRI	Not routinely recommended
Pathology	Ultrasound guided biopsy	
	Core needle biopsy	
	Fine needle aspiration	Pathologic investigation for palpable breast lesions
Axillary lymph node biopsy	Sentinel lymph node biopsy	
	Lymph node biopsy	
Histology	ER, PR and HER2 determination	

7. Management of localised disease

Management of localised cancer covers surgery, hormonal and radiation therapy. Both Lobular carcinoma in situ (LCIS) and Ductal carcinoma in situ are classified as localised disease. Both conditions are classified as Stage 0 diseases according to the TNM classification method[9].

7.1 Surgery

7.1.1 Surgery for breast cancer in localised disease covers both lumpectomy and mastectomy.

7.1.2 Lumpectomy without lymph node surgery together with or without radiation is indicated in women with DCIS. However, the option of lumpectomy alone should be considered only in cases where the patient and the physician view the individual risks as low[15].

7.1.3 Patients with DCIS and evidence of widespread disease (i.e. disease in 2 or more quadrants) require total mastectomy with or without sentinel node biopsy. Although mastectomy provides maximum local control, long-term cause-specific survival with mastectomy appears to be equivalent to that with excision and whole breast irradiation [9, 35].

7.1.4 Both lumpectomy and mastectomy are PMB level of care for women with early breast cancer

7.2 Radiation therapy

7.2.1 Radiation therapy is covered in the treatment of patients with DCIS.

7.2.2 Results of clinical trials have shown that radiotherapy after local excision for DCIS, as compared with local excision alone, reduces the overall number of both invasive and non-invasive recurrences in the ipsilateral breast [36-38].

7.2.3 External beam radiation therapy (EBRT) is indicated for localised disease.

7.2.4 There are 3 types of EBRT: conventional radiotherapy, 3D conformal radiation therapy (3D-CRT) and intensity modulated radiotherapy (IMRT).

7.2.5 The South African Oncology Consortium (SAOC) does not recommend the use of partial breast irradiation as standard therapy because of concerns regarding the long term efficacy of such therapy.

7.2.6 Supporting evidence has shown that the outcome of conventional therapy versus that of 3D-CRT and IMRT do not differ [39, 40].

7.2.7 Conventional radiotherapy is therefore indicated as standard treatment of care.

7.3 Hormone therapy

7.3.1 The use of hormonal therapy in the management of DCIS remains uncertain.

7.3.2 Currently Tamoxifen, Letrozole, Anastrozole and Exemestane are used in the treatment of locally advanced breast cancer.

7.3.3 Tamoxifen is a well-established drug in the treatment of breast cancer and therefore is covered as a PMB level of care.

7.3.4 Aromatase inhibitors are currently being investigated for the adjuvant therapy of DCIS and therefore not covered as a PMB level of care.

Clinical Evidence

Two randomised trials have studied the use of tamoxifen in the management of DCIS. The National Surgical Adjuvant Breast and Bowel Project (NSABP) B-24 trial was a randomised controlled trial of BCS and adjuvant RT with tamoxifen or placebo in 889 women. The median follow up was 13.6 years. The results of the study at 5 years showed that women in the tamoxifen group had fewer breast cancer events (8·2 vs. 13·4%, p=0·0009), fewer cumulative incidence of all invasive breast-cancer events (4·1% vs. 7.2%), fewer incidences of ipsilateral breast (2·1% vs. 4.2%) and contralateral breast (1·8% vs. 2.3%). An increase in the rate of endometrial cancer was reported in the tamoxifen group (1.53 vs. 0.45 per 1000 patients in the placebo group)[41]

The United Kingdom, Australia, and New Zealand DCIS trial was a randomised 2x2 factorial study of RT, tamoxifen or both for locally excised DCIS. Two hundred and forty two women were randomised to receive tamoxifen and radiotherapy. Out of these patients, 25 developed a new breast event, ten DCIS and 14 an invasive cancer. Tamoxifen plus radiotherapy significantly reduced all ipsilateral new breast events (p<0·0001) but had no effect on contralateral new breast events (p=0·2). There were no significant differences in new breast events between patients randomly assigned to radiotherapy and tamoxifen and those randomised to radiotherapy alone. Patients randomised to radiotherapy and tamoxifen had significantly reduced ipsilateral new breast events compared with those randomised to tamoxifen alone (p<0·0001) but not contralateral new breast events (p=0·5). [38].

The benefit from endocrine therapy with tamoxifen or an aromatase inhibitor in low-risk breast cancer (for example small tumours < 2 cm, grade 1, lymph node-negative) is very small and needs to be weighed with the effects on quality of life [15]. Currently, aromatase inhibitors are being investigated for the adjuvant therapy of DCIS and therefore should not be used in routine care [42].

7 .4 Surveillance/Follow-up

7.4.3 Follow-up of patients with localised disease includes interval history and physical examinations every 6 to 12 months for 5 years and then annually as well as yearly diagnostic mammography.

7.4.4 Patients treated with breast-conserving therapy should have follow-up mammography performed 6 to 12 months after completion of breast-conserving radiation therapy.

7.4.3 Ultrasound or MRI is not offered routinely post-treatment in patients who have been treated for early invasive breast cancer or DCIS [8, 9, 15].

8. Management of locally advanced disease

8.1 Patients with locally advanced disease include those with operable (Stage I, IIA, IIB, IIIA: T0 -T3 with a N1-2; N2 with any T1–T3) and inoperable disease at presentation (Stage IIIB: T4a, skin; T4b, chest wall; T4c (a1b) with N1-N2) and those with inflammatory disease (Stage IIIC: N3 with any T, T4d)[9, 43].

8.2 The treatment of locally advanced breast cancer includes a combination of systemic chemotherapy, surgery, hormonal therapy and radiotherapy to optimize the chance of cure[44].

8.3 Neo- Adjuvant Chemotherapy

8.3.1 Neo- Adjuvant Chemotherapy is considered for women with large clinical stage IIA, stage IIB and T3 N1 M0 tumours and Stage IIIB: T4a, skin; T4b, chest wall; T4c (a1b) with N1-N2).

8.3.2 The main goal of neoadjuvant chemotherapy is to enhance surgical options and breast conservation in women with stage 2 or 3 breast cancer who are not candidates for breast conservation [8, 45].

8.3.3 Pre- or postoperative chemotherapy has been shown to have no impact on treatment outcomes on operable cases.

8.3.4 SAOC recommends FAC&PAC, FAC and CMF as a neo-adjuvant breast cancer treatment.

Table 3: Neo-adjuvant chemotherapy for locally advanced disease

Medicine	Indication
Fluorouracil/Doxorubicin,/Cyclophosphamide Paclitaxel/Doxorubicin,/Cyclophosphamide (FAC & PAC)	Neo-adjuvant breast cancer
Fluorouracil/Doxorubicin,/Cyclophosphamide (FAC)	Neo-adjuvant breast cancer
Cyclophosphamide/Methotrexate/ Fluorouracil (CMF)	Neo-adjuvant breast cancer

8.4 Surgery

8.4.1 Mastectomy with axillary lymph node dissection or breast-conserving therapy with lumpectomy, axillary dissection and whole breast irradiation are indicated as a primary breast treatment of women with stage I and stage II breast cancers[9].

8.4.2 Randomised control trail (RCTs) comparing breast conserving surgery with mastectomy found no significant difference in terms of survival or recurrence of disease.

8.4.3 Bilateral mastectomy of un-diseased breast is excluded as a PMB level of care.

8.5 Surgery to the Axilla

8.5.1 Axillary Lymph Node surgery is indicated if there is an axillary disease. The intention of axillary clearance is to prevent axillary relapse.

8.5.2 Axillary lymph node sampling or clearance may also be used for staging; however axillary lymph node clearance may constitute overtreatment in some patients.

8.6 Adjuvant Chemotherapy

7.5.1 Adjuvant chemotherapy is indicated in patients with operable and inoperable disease [8, 9, 15, 46].

Table 4: Adjuvant chemotherapy for locally advanced disease

Medicine	Indication	Comment
Doxorubicin,/Cyclophosphamide(AC)	Low risk adjuvant breast cancer	
Fluorouracil/Doxorubicin,/Cyclophosphamide (FAC)	Low adjuvant breast cancer	
Cyclophosphamide/Methotrexate/ Fluorouracil (CMF)	Low adjuvant breast cancer	
Fluorouracil/Epirubicin/Cyclophosphamide (FEC) Docetaxel	High risk adjuvant breast cancer	Node positive fit patients
Paclitaxel/Doxorubicin,/Cyclophosphamide (PAC)	High risk adjuvant breast cancer	Younger patients with higher risk of relapse

Doxorubicin,/Cyclophosphamide (AC)		
Fluorouracil/Doxorubicin,/Cyclophosphamide (FAC)	High risk adjuvant breast cancer	
Doxorubicin 75 & CMF 21	High risk adjuvant breast cancer	
Cyclophosphamide/ Epirubicin/ Fluorouracil (CEF) 28	High risk adjuvant breast cancer	Highly selected high risk patients, ER-PgR- Her2+++; node positive

8.7 Hormonal therapy

8.7.1 Patients with invasive breast cancers that are ER- or PR- positive are considered for adjuvant endocrine therapy regardless of patient age, lymph node status, or whether adjuvant chemotherapy is to be administered. [9, 15].

8.7.2 Tamoxifen is indicated for 10 years in patients with non-metastatic hormone receptor positive breast cancer.

8.7.3 Aromatase inhibitors are indicated after 2-3 years of Tamoxifen in intermediate and high-risk patients, or after completing 5 years of Tamoxifen

8.7.4 LHRH AGONIST (Goserelin, Zoledronic acid) + Aromatase Inhibitors are indicated for premenopausal with Tamoxifen contraindication

Table 5: Hormonal therapy for locally advanced disease

Medicine	Comment
Tamoxifen	Adjuvant Tamoxifen for 10 years in patients with non-metastatic hormone receptor positive breast cancer
Anastrozole	Postmenopausal women with ER-positive early invasive breast cancer who are high risk and who have been treated with Tamoxifen for 2–3 years.
Letrozole	Postmenopausal women with ER-positive early invasive breast

	cancer who are high risk and who have been treated with Tamoxifen for 2–3 years.
Exemestane	Postmenopausal women with ER-positive early invasive breast cancer who are high risk and who have been treated with Tamoxifen for 2–3 years.
LHRH Agonist (Goserelin, Zoledronic acid) + Aromatase Inhibitors	Premenopausal with Tamoxifen contraindication

Clinical Evidence

Evidence from the ATAC trial showed anastrozole to be an effective and well-tolerated endocrine option for the treatment of postmenopausal patients with early breast cancer. The randomized, double-blind trial, compared tamoxifen (20 mg) with anastrozole (1 mg) alone, and the combination of anastrozole plus tamoxifen (combination), as adjuvant endocrine treatment for postmenopausal patients with early breast cancer. A total of 9366 patients with operable invasive breast cancer following completion of primary therapy were included in the study. Median duration of therapy was 30.7 months and median follow-up was 33.3 months. The results of the study showed a significant improvement in disease free survival (DFS) (hazard ratio (HR) =0.81, 95% confidence interval (CI) (0.71-0.96), P=0.013) and time to relapse in the anastrozole compared with tamoxifen (HR=0.79, CI (0.67-0.94), P=0.008), which improved even further in the ER+ and/or PR+ subgroup (HR=0.73, CI (0.59-0.90), P=0.003). The incidences of hot flushes, thromboembolic events, Ischaemic cerebrovascular events, vaginal bleeding/discharge and endometrial cancer were significantly reduced with anastrozole compared with tamoxifen (P<0.03 for all). Musculoskeletal disorders and fractures were significantly reduced in patients receiving tamoxifen compared with those on anastrozole (P<0.03 for both). No increase in hip fractures was seen for anastrozole versus tamoxifen (11 versus 13, respectively[47].

Evidence from the BIG 1-98 phase III, double-blind trial of 8010 postmenopausal showed that women with endocrine-responsive early breast cancer had a reduction in breast cancer recurrence and mortality when using letrozole monotherapy when compared to tamoxifen. The monotherapy

comparison included patients randomized to tamoxifen × 5 years (n=2459) or letrozole × 5 years (n=2463).The results of the study showed however that sequential treatments involving tamoxifen and letrozole does not improve outcome when compared with letrozole monotherapy[48].

The results of a double-blind, randomized trial to test whether, after two to three years of tamoxifen therapy, switching to exemestane was more effective than continuing tamoxifen therapy for the remainder of the five years of treatment showed that exemestane therapy significantly improved disease-free survival as compared with the standard five years of tamoxifen treatment. A total of 4742 patients were enrolled in the study. After a median follow-up of 30.6 months, 183 events were recorded in the exemestane group and 266 in the tamoxifen group. Overall survival was not significantly different in the two groups, with 93 deaths occurring in the exemestane group and 106 in the tamoxifen group. Severe toxic effects of exemestane were rare. Contra lateral breast cancer occurred in 20 patients in the tamoxifen group and 9 in the exemestane group (P=0.04)[49].

8.8 Radiation therapy

8.8.1 After mastectomy and axillary dissection, radiotherapy has been shown to reduce both recurrence and breast cancer mortality in women with one to three positive lymph nodes in clinical trials[50, 51].

8.8.2 External beam radiation therapy is indicated for localised disease. There are 3 types of EBRT: conventional radiotherapy, 3d conformal radiation therapy (3d-CRT) and intensity modulated radiotherapy.

8.8.3 The South African Oncology Consortium does not recommend the use of partial breast irradiation as standard therapy because of concerns regarding the long term efficacy of such therapy.

8.8.4 Supporting evidence has shown that the outcome of conventional therapy versus that of 3d-CRT and IMRT do not differ.

8.8.5 Conventional radiotherapy is therefore covered as a PMB level of care.

8.9 Follow up

8.9.1 The purpose of long term follow up is to monitor disease progression, to assess and encourage adherence to adjuvant endocrine therapy, to encourage active lifestyle and maintenance of ideal body weight (20-25 BMI) and to manage chemotherapeutic adverse events.

8.9.2 History and physical exam every 4-6 months for 5 years, then every 12 months is PMB level of care.

8.9.3 Mammography every 12 months is PMB level of care.

8.9.4 Annual gynaecologic assessment every 12 months if uterus present is PMB level of care for women on Tamoxifen

8.9.5 Women on an aromatase inhibitor or who experience ovarian failure secondary to treatment are monitored for bone health with a bone mineral density determination at baseline and periodically thereafter.

9 . Breast Replacement options

9.1 Breast replacement option is a PMB level of care for women who have undergone mastectomy.

9.2 An external prosthesis can be used for women who decide that breast reconstruction isn't right for them but still want a breast shape.

9.3 Implants and/or flaps are PMB level of care for women who have undergone mastectomy. Deep Inferior Epigastric Perforators (DIEP) flap is not covered as a PMB level of care.

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