Cancer Treatments Subcommittee of PTAC meeting held 20 August 2010

(minutes for web publishing)

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Note that this document is not necessarily a complete record of the Cancer Treatments Subcommittee meeting; only the relevant portions of the minutes relating to Cancer Treatments Subcommittee discussions about an Application or PHARMAC staff proposal that contain a recommendation are generally published.

The Cancer Treatments Subcommittee may:

(a) recommend that a pharmaceutical be listed by PHARMAC on the Pharmaceutical Schedule and the priority it gives to such a listing;
(b) defer a final recommendation, and give reasons for the deferral (such as the supply of further information) and what is required before further review; or
(c) recommend that PHARMAC decline to list a pharmaceutical on the Pharmaceutical Schedule.

These Subcommittee minutes were reviewed by PTAC at its meeting on 4 & 5 November 2010, the record of which is available on the PHARMAC website.

Contents

1 Rituximab for chronic lymphocytic leukaemia

1.1 The Subcommittee reviewed an application from Roche Products (NZ) Ltd for the funding of rituximab (Mabthera) for patients with chronic lymphocytic leukaemia (CLL). Members noted that the application had been reviewed by PTAC at its May 2010 meeting.

1.2 The Subcommittee noted that PTAC had recommended funding of rituximab for first-line treatment of CLL and relapsed CLL disease in rituximab-naïve patients with medium and low priority respectively. Members focussed their discussion on these two groups of patients. Members agreed with PTAC's recommendation that funding of relapsed CLL disease following previous rituximab treatment should be declined

1.3 The Subcommittee noted that while the application was for treatment of CLL, this also included small lymphocytic lymphoma (SLL), members considered these the same disease but for location of cancer cells.

1.4 The Subcommittee noted that CLL was a chronic disease with an evolving treatment algorithm. Members considered that a watch and wait approach was taken in early stage disease patients with chemotherapy being initiated in patients with Binet stage B and C disease or in patients with Binet stage A and evidence of progression.

1.5 The Subcommittee considered that currently standard first-line treatment for fitter patients with CLL in New Zealand consisted of fludarabine and cyclophosphamide (FC) chemotherapy which is expected to induce complete response in 20-40% of patients with duration of remission in the region of 3 to 4 years.

1.6 The Subcommittee discussed evidence from a number of phase II and phase III studies for the use of rituximab in patients with CLL. Members noted that the dose of rituximab used in the treatment of CLL was higher than used in lymphoma (up to 500 mg/m^2 compared with 375 mg/m^2), and that this was likely needed because of several factors including lower CD20 expression on CLL clones.

1.7 The Subcommittee considered key evidence from 2 randomised controlled studies: the CLL-8 study *(Hallek Blood (ASH Annual Meeting Abstracts) 2008 112: Abstract 325 and Hallek Blood (ASH Annual Meeting Abstracts) 2009 114: Abstract 535)* in patients with de novo disease and the REACH study *(Robak et al. J Clin Oncol. 2010 Apr 1;28(10):1756-65)* in patients with relapsed disease. Both studies compared treatment with six cycles of rituximab plus FC (R-FC) with six cycles of FC alone. Members noted that the CLL-8 study had not yet been published in a peer reviewed journal and that the publically available evidence presented comprised two abstracts and a slide presentation.

1.8 The Subcommittee considered that the CLL-8 study enrolled a relatively good-prognosis population (median age 61, low median cumulative illness rating scale score and few comorbidities); members considered that this population was not entirely representative of the general CLL population, for example most patients presenting with CLL in the clinic would be greater than 65 years of age and may have significant comorbidities.

1.9 The Subcommittee considered that evidence from CLL-8 demonstrated that the addition of rituximab to FC chemotherapy improved median progression-free survival by 19 months and at 3 years more patients treated with FCR were alive (84%) compared with patients treated with FC (79%). Members considered that the greatest benefits from treatment were in patients with Binet stage A and B disease, with lesser response seen in patients with Binet stage C disease. Members noted that patients with chromosome 17p deletion CLL do not appear to respond to addition of rituximab to FC.

1.10 The Subcommittee noted that the REACH study enrolled patients who had relapsed disease following prior first line single agent treatment with fludarabine or chlorambucil or treatment with a combination regimen containing an alkylating agent. Members noted that patients could not have received prior FC treatment. Members noted that like the CLL-8 study the REACH study had also enrolled good prognosis patients most likely to respond. Members considered that this study demonstrated that the addition of rituximab to FC chemotherapy improved median progression-free survival advantage by 10 months at 2 years follow up however there was no improvement in overall survival at that time with the majority of patients still alive in both treatment groups.

1.11 The Subcommittee considered that rituximab was generally well tolerated but was associated with a higher incidence of hematologic adverse events, particularly neutropaenia, however it was not associated with increased infection rate.

1.12 The Subcommittee **recommended** that rituximab should be funded for patients with de novo CLL disease and rituximab naïve patients with relapsed disease under Special Authority criteria as follows:

> **Rituximab – PCT only – Specialist - Special Authority for Subsidy**
> **Initial application — (CLL)** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:
> All of the following
> 1. The patient has Binet stage A, B or C chronic lymphocytic leukaemia; and
> 2. The patient is rituximab treatment naïve; and
> 3. Either
> 3.1 The patient is treatment naïve; or
> 3.2 The patient's disease has relapsed following prior treatment with single agent fludarabine, chlorambucil or combination treatment containing an akylating agent (excluding fludarabine plus cyclophosphamide; and
> 4. The patient has good performance status (WHO/ECOG grade 0-1); and
> 5. The patient has good renal function (creatinine clearance ≥ 60 ml/min); and
> 6. The patient does not have chromosome 17p deletion CLL; and
> 7. Rituximab to be administered in combination with fludarabine and cyclophosphamide for a maximum of 6 treatment cycles;
> 8. It is planned that the patient receives full dose intravenous or dose equivalent oral fludarabine (25 mg/m2 IV for 3 days) and cyclophosphamide (250 mg/m2 IV for 3 days)

1.13 The Subcommittee gave this recommendation a high priority

1.14 The Subcommittee considered that although a significant number of patients were diagnosed each year with CLL not all would be considered suitable for treatment with rituximab in combination with FC. Members considered that approximately 50 patients would be treated in the first year.

1.15 The Decision Criteria particularly relevant to this recommendation are *(i) The health needs of all eligible people within New Zealand; (iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things; (iv) The clinical benefits and risks of pharmaceuticals; (v) The cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services, (vi) The budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule and (viii) The Government's priorities for health funding, as set out in any objectives notified by the Crown to PHARMAC, or in PHARMAC's Funding Agreement, or elsewhere.*

2 Azacitidine (Vidaza) for myelodysplastic syndromes

2.1 The Subcommittee reviewed an application from Celgene Pty Ltd for the funding of azacitidine (Vidaza) for the treatment of patients with intermediate-2 or high risk Myelodysplastic Syndromes (MDS), Chronic Myelomonocytic Leukaemia (CMML) or Acute Myeloid Leukaemia (AML). Members noted that this application was prompted by a review of EC applications it conducted at its November 2009 meeting. Members noted that the application had been reviewed by PTAC at its August 2010 meeting but that minutes from that meeting were not yet available.

2.2 The Subcommittee noted that MDS encompassed a heterogeneous group of closely related clonal hematopoietic disorders. Members considered that MDS was an incurable disease that was often difficult to treat and there were was an unmet clinical need for effective treatment options.

2.3 The Subcommittee considered that currently New Zealand MDS patients requiring treatment would receive either high dose induction chemotherapy, if they were younger patients with good performance status, or best supportive care. Members considered that low dose cytarabine (Ara-C) was not often used despite its ease of administration and increasing evidence of good efficacy.

2.4 The Subcommittee reviewed evidence from 2 key clinical studies AZA-001 (Fenaux et al 2009) and CALGB 9221 (Silverman et al 2002) comparing azacitidine with conventional care (including BSC) in patients with MDS. Members considered that overall the evidence demonstrated that azacitidine treatment resulted in an approximate 2 fold increase in overall survival duration compared with conventional care (BSC, low-dose cytarabine, or high dose chemotherapy).

2.5 The Subcommittee further noted that treatment with azacitidine reduced the number of transfusions required, and total units administered, in patients per annum compared with conventional care.

2.6 The Subcommittee considered that there was some uncertainty about the number of patients who would be treated if azacitidine were funded. Members considered that MDS was relatively common (and perhaps currently under-reported) and it was difficult to clearly define a subset of patients who would most benefit from treatment.

2.7 The Subcommittee noted that the clinical evidence was of relatively short duration for what was a chronic disease and considered it reasonable to model longer term outcomes (beyond 24 months) using a straight line method because at present there was no evidence of a plateau in survival.

2.8 The Subcommittee **recommended** that azacitidine should be funded for patients with intermediate-2 or high risk MDS, CMML or MDS related – AML under Special Authority criteria as follows:

> Azacitidine – PCT only – Specialist - Special Authority for Subsidy
> Initial application — only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:
> All of the following
> 1 Either:
>
> 1.1 The patient has International Prognostic Scoring System (IPSS) intermediate-2 or high risk myelodysplastic syndrome; or
> 1.2 The patient has Chronic Myelomonocytic Leukaemia (10%-29% marrow blasts without myeloproliferative disorder); or
> 1.3 The patient has Acute Myeloid Leukaemia with 20-30% blasts and multi-lineage dysplasia, according to World Health Organisation Classification (WHO); and
>
> 2. The patient has performance status (WHO/ECOG) grade 0-2; and
> 3. The patients does not have secondary myelodysplastic syndrome resulting from chemical injury or prior treatment with chemotherapy and/or radiation for other diseases; and
> 4. The patient has an estimated life expectancy of at least 3 months

2.9 The Subcommittee give this recommendation a low priority.

2.10 The Subcommittee considered that although azacitidine improved survival duration it was a palliative treatment and considered it was very costly given its relatively modest overall Quality Adjusted Life Year gains. Members were disappointed with the high price and considered that if the costs were reasonable it would recommend azacitidine be funded with a high priority. Members thought that the patent for azacitidine may expire shortly which would likely reduce its price significantly and recommended that PHARMAC investigate its patent status further.

2.11 The Decision Criteria particularly relevant to this recommendation are: *(i) The health needs of all eligible people within New Zealand; (iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things; (iv) The clinical benefits and risks of pharmaceuticals; (v) The cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services, (vi) The budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule, and (viii) The Government's priorities for health funding, as set out in any objectives notified by the Crown to PHARMAC, or in PHARMAC's Funding Agreement, or elsewhere.*

3 Pipobroman for polycythemia rubra vera and essential thrombocythemia

3.1 The Subcommittee reviewed an application from a clinician for the listing of pipobroman on the Pharmaceutical Schedule for the treatment of patients with polycythaemia rubra vera (PV) or essential thrombocythaemia (ET) whose disease had not responded to hydroxyurea (HU) or for patients intolerant to HU treatment. Members noted that this application was prompted by a review of EC applications it conducted at its November 2009 meeting. Members noted that the application had been reviewed by PTAC at its August 2010 meeting but minutes from that meeting were not yet available.

3.2 The Subcommittee considered that both PV and ET were rare, chronic, incurable myeloproliferative diseases with the main causes of death being thrombotic events and haemorrhage in the short term and transformation to Acute Myeloid Leukaemia (AML) and myelofibrosis in the longer term. Members considered that the main goal of treatment for PV and ET was to reduce the risk of vascular events.

3.3 The Subcommittee considered that current first line treatment options for PV and ET comprised phlebotomy and low dose aspirin or hydroxyurea (HU), with most patients receiving anagrelide as second line treatment if their disease failed to respond to HU, or if they were intolerant of HU.

3.4 The Subcommittee reviewed evidence from a large number of studies; members considered that in general the quality and strength of the evidence was poor, with 8 single arm cohort studies and only 2 randomised controlled studies. The Subcommittee considered that the best quality evidence was from the two randomised controlled studies: one comparing HU and anagrelide in ET patients (Harrison et al 2005) and one comparing HU and pipobroman in PV patients (Najain and Rain 1997).

3.5 The Subcommittee noted that all studies were conducted in treatment naïve patients, and there were no comparative trials comparing pipobroman with anagrelide, and therefore it was only able to make indirect comparisons of the safety and efficacy of pipobroman and anagrelide.

3.6 The Subcommittee considered that HU, anagrelide and pipobroman had similar efficacy therefore the choice of treatment was largely driven by other factors, namely tolerability, longer term treatment associated AML risk and cost.

3.7 The Subcommittee considered that when taking these factors into account HU remained the first line treatment of choice. Members considered that it was difficult to determine from the evidence available the best second line treatment choice.

3.8 The Subcommittee considered that anagrelide had a higher risk of thrombotic or haemorrhagic events whereas pipobroman may have an increased risk for long term AML transformation; however, members considered that the evidence for this was unclear. Given these differences members considered that they would most likely use anagrelide in younger patients but pipobroman in older patients.

3.9 The Subcommittee considered that although there were no studies examining the use of pipobroman for the second line treatment of PV or ET patients it was reasonable to

consider that pipobroman would have activity following HU treatment given its different mode of action, and patients intolerant to HU would be similar to a treatment naive population.

3.10 The Subcommittee noted that at the prices indicated by the applicant it appeared that that pipobroman was cheaper than anagrelide; however, members noted that pipobroman is not approved by MedSafe and there is currently no supplier of the product in New Zealand. Members noted that without a NZ supplier PHARMAC would be unable to secure pricing or supply of pipobroman.

3.11 The Subcommittee **recommended** that pipobroman should be funded for the treatment of polycythaemia rubra vera or essential thrombocythaemia patients refractory to, or intolerant of, hydroxyurea. The Subcommittee gave this recommendation a medium priority.

3.12 The Decision Criteria particularly relevant to this recommendation are: *(i) The health needs of all eligible people within New Zealand; (iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things; (iv) The clinical benefits and risks of pharmaceuticals; (vi) The budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule.*

4 Bevacizumab CUA

4.1 The Subcommittee considered a paper from PHARMAC staff regarding the cost-utility analysis (CUA) for bevacizumab (Avastin) for the neoadjuvant treatment of patients with metastatic colorectal cancer (mCRC) in whom metastases are confined to the liver only.

4.2 The Subcommittee noted that it had reviewed an application from Roche Products (NZ) Ltd for the funding of bevacizumab at its April 2010 meeting and recommended, with medium priority, that it be funded under Special Authority criteria as neoadjuvant treatment in combination with chemotherapy for up to 4 cycles in patients with mCRC confined to the liver.

4.3 The Subcommittee considered that the aim of treating with neoadjuvant bevacizumab in this setting was to improve complete resection rates and potential cure. However, members noted that the evidence was weak and because of the lack of appropriate comparative data a number of assumptions needed to be made in the CUA modelling and analysis.

4.4 The Subcommittee considered that most patients with an R0 resection and event free survival at 3 – 5 years post surgery would survive long term and would therefore be considered cured, members considered that this would comprise approximately 70-80% of all patients with mCRC confined to the liver who achieved R0 resection.

4.5 The Subcommittee considered it reasonable to model resection rate gains using evidence from the NO16966 study (Okines et al 2009). Members noted that in this study 6.3% of patients treated with bevacizumab plus chemotherapy achieved R0 resection compared in the 4.9% of patients treated with chemotherapy only.

4.6 The Subcommittee noted that from the current evidence it appears that in patients who achieve R0 resection long term outcome was not influenced by the type of neoadjuvant chemotherapy given prior to surgery, in other words the outcome is mostly driven by the success of the surgery. Therefore, members considered it was reasonable to assume similar outcomes for both arms in the CUA model for those patients achieving R0 resection.

4.7 The Subcommittee **recommended** that PHARMAC staff seek further advice regarding R0 resection rates and survival outcomes from a liver surgeon and provided relevant contact details.

5 Gemcitabine for macroscopically resected pancreatic cancer

5.1 The Subcommittee considered further information regarding an application from the New Zealand Association of Cancer Specialists – Gastrointestinal Special Interest Group (NZACS-GISIG) to widen access to gemcitabine to allow for its use as adjuvant treatment of macroscopically resected pancreatic cancer.

5.2 The Subcommittee noted that the application had previously been considered by PTAC and CaTSoP in February 2009 and both committees had recommended funding, based on the clinical evidence available at that time, with a high priority. However, members noted that following review of new evidence at its November 2009 meeting PTAC changed its recommendation and recommended that the application be declined. The Subcommittee reviewed PTAC's November minute and further correspondence from the NZACS-GISIG at its April 2010 meeting and considered that it would be appropriate for it to review the application again, including the new evidence and cost-utility analysis.

5.3 The Subcommittee reviewed a slide presentation from a phase III study (ESPAC-3 v2) of 1,088 patients comparing adjuvant treatment with 5-fluorouracil (5FU) and folinic acid (FA; as per the Mayo regimen) with gemcitabine in patients with resected pancreatic cancer presented at the American Society of Clinical Oncology meeting in June 2009. Members noted that the study had not yet been published in full. The Subcommittee also reviewed further correspondence from the applicants regarding this study and a cost-utility analysis undertaken by PHARMAC staff.

5.4 The Subcommittee considered that in the ESPAC-3 study at a median follow-up of 34 months there was no difference in median survival between the 5FU (Mayo) and gemcitabine treatment groups. However, members noted that in New Zealand oncologists did not use the Mayo 5FU regimen because it is considered too toxic and is relatively intensive to deliver. Members considered that currently in New Zealand patients with resected pancreatic cancer would either receive best supportive care treatment or weekly 5FU/FA.

5.5 The Subcommittee noted that, unlike in the colorectal cancer setting, there was no evidence supporting the equivalence of the Mayo and weekly 5FU/FA regimens in pancreatic cancer. Members considered that there were biological differences between the colorectal and pancreatic cancers that made the extrapolation of evidence between the two cancer types inappropriate. Therefore, members considered that the use of weekly 5FU in patients with pancreatic cancer was not evidence based or appropriate.

5.6 The Subcommittee noted that gemcitabine was currently funded for patients with metastatic pancreatic cancer; members considered that it would probably be more cost effective to use gemcitabine in the adjuvant setting rather than the metastatic setting because at least in this setting some patients would be cured.

5.7 The Subcommittee **recommended** that gemcitabine be funded for the adjuvant treatment of macroscopically resected pancreatic cancer.

5.8 The Subcommittee noted that there was no evidence to support gemcitabine retreatment in the metastatic setting following relapse after adjuvant gemcitabine treatment, therefore, it **recommended** that the Special Authority restriction currently applying to gemcitabine for advanced pancreatic cancer be amended to exclude the funding in patients who have previously received adjuvant gemcitabine.

5.9 Members considered that moving gemcitabine to the adjuvant setting would perhaps increase the total number of patients receiving funded treatment by 50%, compared with the number currently funded.

5.10 The Subcommittee **recommended** that gemcitabine should be funded for the adjuvant treatment of pancreatic cancer under the Special Authority criteria as follows:

> Gemcitabine – PCT only – Specialist - Special Authority for Subsidy
> Initial application — (Pancreatic Cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:
> Either
> 1 All of the following;
> 1.1 The patient has macroscopically resected (R0) pancreatic carcinoma; and
> 1.2 Adjuvant gemcitabine to be administered for a maximum of 6 cycles; or
> 2. All of the following:
> 2.1 The patient has advanced pancreatic carcinoma; and
> 2.2 The patient is gemcitabine treatment naïve; and
>
> Renewal - (Pancreatic Cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:
> Either:
> 1 The patient has received gemcitabine for advanced pancreatic carcinoma; and
> 2 The patient has not received gemcitabine for adjuvant treatment pancreatic carcinoma; and
> 3 The patient requires continued therapy.

5.11 The Subcommittee give this recommendation a high priority.

5.12 The Decision Criteria relevant to this recommendation are: *(i) The health needs of all eligible people within New Zealand; (iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things; (iv) The clinical benefits and risks of pharmaceuticals; (v) The cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services (vi) The budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule, (viii) The Government's priorities for health funding, as set out*

in any objectives notified by the Crown to PHARMAC, or in PHARMAC's Funding Agreement, or elsewhere.

6 Docetaxel for early breast cancer

6.1 The Subcommittee reviewed an application and related correspondence from the New Zealand Association of Breast Cancer Specialists – Breast Special Interest Group (NZACS-BSIG) for the widening of funded access to docetaxel for the adjuvant treatment of patients with early stage breast cancer.

6.2 The Subcommittee noted that the application was reviewed by PTAC at its February 2010 meeting where it recommended the application be declined. At its April 2010 meeting the Subcommittee noted that this application had not been reviewed by the Subcommittee and requested that it review the application.

6.3 The Subcommittee noted that it had previously recommended funding of at least one taxane (paclitaxel or docetaxel) for patients with node positive early breast cancer, noting that the efficacy and toxicity differences between them were not significant enough to prefer one over the other but that if the overall costs were similar it would prefer both to be funded. Members noted that in 2006 PHARMAC widened access to paclitaxel but not docetaxel because it was unlikely to be cost-effective due to its significantly higher price compared with paclitaxel at that time. Members noted that in 2007 docetaxel was funded for patients with HER 2 positive early breast cancer when given concurrently with trastuzumab.

6.4 The Subcommittee considered that currently in New Zealand patients requiring adjuvant taxane treatment for early breast cancer would receive weekly paclitaxel in combination with anthracycline based chemotherapy, mainly doxorubicin and cyclophosphamide (AC).

6.5 The Subcommittee reviewed evidence from ECOG 11-99, a randomised, controlled study comparing adjuvant paclitaxel with docetaxel both given every three weeks for four cycles or weekly for 12 weeks (Sparano et al N Engl J Med 2008; 358: 1663-71) in patients with node–positive or high-risk, lymph node–negative early breast cancer. The Subcommittee considered that the evidence demonstrated that weekly paclitaxel and docetaxel every three weeks had similar efficacy with both having better efficacy than either 3 weekly paclitaxel or weekly docetaxel.

6.6 The Subcommittee considered that although the toxicity profiles were different; weekly paclitaxel being associated with higher rates of peripheral neuropathy and 3 weekly docetaxel being associated with higher rates of neutropaenia, overall these toxicity differences did not lead it to prefer one taxane over the other in the general early breast cancer population where adjuvant anthracycline-based chemotherapy was standard treatment. However, members noted that, unlike docetaxel, there was no evidence supporting the use of paclitaxel in combination with anthracycline sparing adjuvant chemotherapy, therefore, the Subcommittee considered it would be appropriate to fund docetaxel as the taxane of choice for patients in whom anthracycline treatment is contraindicated.

6.7 The Subcommittee noted that currently the only evidence-based funded adjuvant treatment option for early breast cancer patients unable to receive anthracylines is combination cyclophosphamide, methotrexate and 5FU chemotherapy (CMF) however, members considered this regimen to be inferior to taxane-based chemotherapy, including the anthracycline sparing taxane regimen of docetaxel in combination with cyclophosphamide given for four cycles.

6.8 The Subcommittee **recommended** the Special Authority criteria for docetaxel for the treatment of patients with early breast cancer be amended as follows (changes in bold):

> Docetaxel – PCT only – Specialist - Special Authority for Subsidy
> Initial application — only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:
>
> [….]
> 3 ~~Both~~: The patient has early breast cancer; and
> 3.1 ~~The patient has early breast cancer; and~~ **Either**
> **3.2.1** Docetaxel is to be given concurrently with trastuzumab; or
> **3.2.2 Both:**
> **3.2.2.1 Docetaxel is to be given in combination with cyclophosphamide for 4 cycles; and**
> **3.2.2.2 Either**
> **3.2.2.2.1 The patient has cardiomyopathy contraindicating anthracycline treatment; or**
> **3.2.2.2.1 The patient has received prior anthracycline-based chemotherapy contraindicating further anthracycline treatment**
> [….]

6.9 The Subcommittee give this recommendation a high priority.

6.10 The Subcommittee considered that few patients would meet the proposed funding criteria, approximately 50 per year, but that there was an unmet need for the funding of a suitable taxane for these patients.

6.11 The Decision Criteria relevant to this recommendation are: *(i) The health needs of all eligible people within New Zealand; (iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things; (iv) The clinical benefits and risks of pharmaceuticals; (v) The cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services (vi) The budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule, (viii) The Government's priorities for health funding, as set out in any objectives notified by the Crown to PHARMAC, or in PHARMAC's Funding Agreement, or elsewhere.*