

Interim excerpt from the Record of the Cancer Treatments Advisory Committee meeting held on 8 April 2022 (pending publication of the full meeting record)

This is an excerpt from the meeting record of the Cancer Treatments Advisory Committee (its meeting of 8 April 2022), provided in advance of the full meeting record.

Cancer Treatments Advisory Committee records are published in accordance with the [Terms of Reference](#) for the Pharmacology and Therapeutics Advisory Committee (PTAC) Specialist Advisory Committees 2021.

This document is an excerpt and records only one of the items considered during the Cancer Treatments Advisory Committee meeting.

Advisory Committees make recommendations, including priority, within their therapeutic groups of interest.

The record of this Advisory Committee meeting will be reviewed by PTAC at an upcoming meeting.

Specialist Advisory Committees and PTAC may differ in the advice they provide to Pharmac, including recommendations' priority, due to the committees' different, if complementary, roles, expertise, experience, and perspectives.

Pharmac is not bound to follow the recommendations made below. Applications are prioritised by Pharmac against other funding options and progressed accordingly. The relative priority of any one funding choice is dependent on a number of factors, including (but not limited to) the recommendation of PTAC and/or Specialist Advisory Committees, the mix of other applications being assessed, the amount of funding available, the success of commercial negotiations and/or the availability of clinical data.

1. The role of Specialist Advisory Committees and records of meetings

- 1.1. This interim excerpt of the meeting record of the Cancer Treatments Advisory Committee, provided in advance of the full record of the meeting, is published in accordance with the Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) and Specialist Advisory Committees 2021, available on the Pharmac website at <https://pharmac.govt.nz/assets/2021-Specialist-Advisory-Committee-Terms-of-Reference.pdf>. The Terms of Reference describe, *inter alia*, the establishment, activities, considerations, advice, and the publication of such advice of Specialist Advisory Committees and PTAC.
- 1.2. Conflicts of Interest are described and managed in accordance with section 7.2 of the PTAC Terms of Reference.
- 1.3. The Cancer Treatments Advisory Committee is a Specialist Advisory Committee. The Cancer Treatments Advisory Committee and PTAC and other Specialist Advisory Committees have complementary roles, expertise, experience, and perspectives. The Cancer Treatments Advisory Committee and other Specialist Advisory Committees may therefore, at times, make recommendations for

treatments for Cancer that differ from PTAC's, including the priority assigned to recommendations, when considering the same evidence. Likewise, PTAC may, at times, make recommendations for treatments for Cancer that differ from the Cancer Treatments Advisory Committee's, or Specialist Advisory Committees may make recommendations that differ from other Specialist Advisory Committees'.

Pharmac considers the recommendations provided by both the Cancer Treatments Advisory Committee and PTAC and any other relevant Specialist Advisory Committees when assessing applications for treatments for cancer.

2. Immune checkpoint inhibitors for locally advanced or metastatic non-small cell lung cancer

Application

- 2.1. The Advisory Committee reviewed a request from Pharmac seeking advice regarding the use of immune checkpoint inhibitors (ICI) for the treatment of metastatic non-small cell lung cancer (mNSCLC).
- 2.2. The Advisory Committee took into account, where applicable, Pharmac's relevant decision-making framework when considering this agenda item.

Discussion

- 2.3. The Advisory Committee reviewed a paper from Pharmac seeking updated clinical input regarding the landscape associated with immune checkpoint inhibitors for the treatment of locally advanced or metastatic non-small cell lung cancer (mNSCLC) in New Zealand. The Committee noted that Pharmac sought advice relating to the use and evidence associated with immune checkpoint inhibitors (ICIs) for the treatment of different stages of NSCLC in light of previous considerations of ICIs for this patient group, preference of agents and treatment regimens for different lines of treatment, and potential budget impacts.
- 2.4. The Committee noted that the primary evidence for use of ICIs in NSCLC in previous funding applications comes from the following trials:
 - 2.4.1. First-line monotherapy for NSCLC patients
 - 2.4.1.1. [KEYNOTE-024](#) - Reck et al. NEJM 2016;375:1823-33: Pembrolizumab versus platinum-based chemotherapy for previously untreated patients with advanced NSCLC with PD-1 expression of >50% and no EGFR mutation.
 - 2.4.1.2. [IMPOWER110](#) - Conference abstract: Spigel DR, et al. Ann Oncol 2019; 30(Suppl_5):mdz293: Atezolizumab versus platinum based chemotherapy for patients with previously untreated, stage four NSCLC with a PD-L1 expression of greater than 1%. (205 patients with PD-L1 expression > 50%).
 - 2.4.1.3. [KEYNOTE-042](#) - Mok TSK et al, Lancet. 2019;393(10183):1819-1830: pembrolizumab monotherapy versus platinum-based chemotherapy in previously untreated mNSCLC in patients with a PD-L1 ≥1%.
 - 2.4.2. First-line combination therapy with chemotherapy, for NSCLC patients
 - 2.4.2.1. [KEYNOTE 407](#) - Paz-Ares et al, N Engl J Med 2018;379:2040-51: pembrolizumab with carboplatin and either paclitaxel or nab-paclitaxel

versus placebo with carboplatin and either paclitaxel or nab-paclitaxel in patients with untreated metastatic stage IV, squamous NSCLC.

- 2.4.2.2. [KEYNOTE189](#) - Gandhi et al, N Engl J Med 2018;378:2078-92: pembrolizumab with pemetrexed in combination with a platinum based agent versus placebo with pemetrexed in combination with a platinum based agent in patients with metastatic non-squamous NSCLC (EGFR or ALK wildtype) who had received no previous treatment for metastatic disease.
- 2.4.2.3. [IMPOWER150](#) - Socinski et al. N Engl J Med.2018;24:2288-301: atezolizumab + bevacizumab + paclitaxel + carboplatin versus atezolizumab + paclitaxel + carboplatin and bevacizumab + paclitaxel + carboplatin for patients with untreated stage IV or recurrent metastatic non-squamous NSCLC (EGFR/ALK included if prior disease progression / side effects from prior TKI use).

2.4.3. Second-line monotherapy for NSCLC patients

- 2.4.3.1. [KEYNOTE-010](#) - Herbst et al, Lancet 2016; 387:1540-50: pembrolizumab monotherapy versus docetaxel in patients with previously treated advanced NSCLC with a PD-L1 expression of greater than $\geq 1\%$.
- 2.4.3.2. [OAK](#) - Rittmeyer et al, Lancet 2017; 389:255-65: atezolizumab versus docetaxel in patients with non-squamous or squamous NSCLC who have received one or two previous cytotoxic treatments (one or more containing platinum-based combination therapies for stage IIIb or stage IV NSCLC).
- 2.4.3.3. [CheckMate 017](#) - Brahmer et al, N Engl J Med 2015;373:123-35: nivolumab versus docetaxel for patients with advanced squamous NSCLC who have progressed following first line chemotherapy.
- 2.4.3.4. [CheckMate 057](#) - Borghaei et al, N Engl J Med 2015;373:1627-39: nivolumab versus docetaxel in patients with advanced non-squamous NSCLC who had progressed on platinum-based doublet-chemotherapy.

- 2.5. The Committee noted that immune checkpoint inhibitors for the treatment of metastatic NSCLC had been reviewed on several occasions by the Committee and emphasised that these prior reviews had detailed the unmet health need for NSCLC patients, equity issues relating to stage at diagnosis and disease specific survival for Māori and Pacific patients, the results of the clinical portfolios for the ICI agents, and the uncertainty regarding PD-L1 testing platforms as well as interpretation of PD-L1 testing results.
- 2.6. The Committee noted that, compared to treatment with docetaxel, the chance of patients being alive at later time points (such as at 18 months) almost doubles with ICI treatment, and that this is a meaningful difference to patients. The Committee noted that the OAK trial reported an 18-month event-free survival rate of 40.04% with atezolizumab compared to 26.9% with docetaxel, while the POPLAR trial ([Fehrenbacher et al. Lancet. 2016;387:1837-46](#)) reported 38.1% and 24.5% 18-month event-free survival rates for atezolizumab and docetaxel, respectively. The Committee noted that in Checkmate 017, the 18-month event-free survival rates were 28.0% and 13.0% for nivolumab and docetaxel, respectively. Similarly, the Committee noted that checkmate 057 reported 18-month event-free survival rates of 39% and 23% for nivolumab and docetaxel respectively.

2.7. The Committee noted that there are differences between Stage IV and locally advanced (Stage III) NSCLC that would impact which patients are considered for treatment with ICI's. The Committee noted that Stage IV disease typically included patients with disease that had spread to another area either within the lung, or to another organ outside the lung. In contrast the Committee noted that those with unresectable locally advanced disease could be considered in two groups; those that can be considered for radical treatment (an intensive course of radiotherapy) and those that are being managed palliatively. The Committee noted that patients with locally advanced disease (Stage III) would be considered for radical treatment in the first line, but part of this patient cohort includes patients who, due to comorbidities or performance status, would not be fit for radical treatment and would therefore be managed palliatively.

2.7.1. The Committee considered that this cohort of patients for whom radical treatment is not considered suitable would likely disproportionately include Māori and Pacific patients, and those from other disadvantaged groups. The Committee considered that these patients (unresectable, locally advanced, for whom radical treatment is not considered suitable), as well as those with metastatic disease (ie stage IV), would encompass the patient group for whom treatment with ICIs would be appropriate, noting the former patient population (radical treatment is considered suitable) would likely be offered treatment with durvalumab. The Committee acknowledged however that this consideration is based on extrapolation of evidence from KEYNOTE-024 and IMPOWER-110, which only included stage IV patients.

2.8. The Committee noted the previous recommendations made for funding of ICIs and considered that these were based on the evidence available at the time of the consideration. The Committee noted that updated progression-free survival and overall survival data has since been made available for many of these studies which has improved the strength of evidence of benefit for these agents over time.

2.8.1. The Committee noted its prior decline recommendation for the use of atezolizumab in combination with bevacizumab/chemotherapy as a first-line combination therapy treatment. The Committee noted decisions made in other international jurisdictions relating to and supporting the use of atezolizumab in this setting and considered its prior decline reflected hesitation around the study design and available data supporting use in this setting rather than specific reservation regarding the likely benefit that atezolizumab could offer as an ICI agent in this context. The Committee considered that it would be willing to reassess the possible benefit offered by atezolizumab if further evidence were to become available, acknowledging that role of bevacizumab (eg atezolizumab with chemotherapy and without bevacizumab) is unclear and has not been proven based on information provided to the Committee to date. The Committee noted that it would also like to review any other ICI agent that could address this unmet need, should a funding application be received.

2.9. The Committee noted the available evidence and considered that it remains appropriate to consider that atezolizumab and pembrolizumab provide the same or similar health benefit for first line NSCLC monotherapy, such that funding of either agent in this line of therapy would be clinically appropriate. The Committee noted updated progression-free survival and overall survival available across the other ICI agents. The Committee considered it reasonable to assume equivalent treatment benefit could be achieved from ICI agents (pembrolizumab, nivolumab and atezolizumab) when funded as second line monotherapy.

- 2.10. The Committee considered the funding and availability of ICI agents internationally and considered it would be reasonable to consider funding of any ICI that has received a positive recommendation from the Committee for NSCLC in the various treatment lines based on likelihood of clinical benefit. The Committee considered that it was appropriate to assess previously assessed ICI agents as having a class effect for the purpose of enabling listing and noted whilst this may apply to new agents, there would still need to be an assessment undertaken of the adequate strength and quality of evidence for any new agent or agent without a positive funding recommendation.
- 2.11. The Committee considered that it would be clinically acceptable to have different ICIs funded in different lines of therapy for NSCLC eg first line monotherapy, first line combination therapy, and second line treatment.
- 2.11.1. The Committee considered that the choice of agent funded in each line was unlikely to change the proportion of which patients access monotherapy versus combination therapy and noted that this would be driven by performance status, prior treatments and PD-L1 testing. The Committee considered that having different agents available in different lines or combinations could easily be managed by clinicians.
- 2.12. The Committee considered that the estimated incidence of first line patients was reasonable but considered that New Zealand based data should be used to estimate the proportion of patients with EGFR mutations and noted a New Zealand based study reported rates of EGFR mutations to be approximately 20% ([Aye et al. Cancer Epidemiol. 2020;69:101847](#)). The Committee considered that there is no good quality New Zealand data reporting the rate of NSCLC patients with ALK mutations, and that the international rate of 5% is appropriate ([Chia et al. Clin Epidemiol. 2014;6:423-32](#)). The Committee considered that, after factoring in the number of patients with stage 1-2 disease that would progress to stage 4, this would result in an annual incident ICI eligible population of approximately 1,021 patients, based on the following assumptions:
- There are 1,506 new NSCLC patients per year in NZ ([Te Aho 2021](#)) 83.5% of whom have locally advanced or metastatic disease at diagnosis ([Lawrenson et al 2018](#))
 - Of these patients, 20% are expected to have rates of EGFR mutations (Aye et al.) and 5% are expected to have ALK+ mutations ([Chia et al.](#)), resulting in 943 patients with neither mutation.
 - In addition to this number, there are expected to be 248 patients with NSCLC diagnosed with stage 1-2 disease, 186 of whom have neither mutation. 42% of this number will progress to stage 3-4 disease ([Sugimura et al 2007](#)), which comes to 78 additional patients
 - In total, it is expected that there will be an annual incident 1,021 eligible patients (943 + 78).
- 2.12.1. The Committee considered that there would be an additional cohort of ICI eligible patients within the first 2-3 years of funding comprised of stage III NSCLC patients who relapse, and who did not receive durvalumab treatment. The Committee considered that this may add an additional 60 patients to the ICI eligible cohort. The Committee noted that stage III patients for whom radical

treatment is not considered suitable and who pre-date the listing of durvalumab would have a poor prognosis and would be captured in stage IV data.

- 2.12.2. The Committee noted that updated data from the 2021 [Te Aho Te Kahu Lung Cancer Quality Improvement Monitoring Report](#) reported that 29.7% of people with NSCLC received systemic anti-cancer therapy. The Committee noted that applying this percentage to the above patient number estimate would result in an incident 303 eligible patients per year. The Committee considered that there would be an increase in use of systemic therapy if an ICI was funded, driven by the increased treatment of patients eligible for monotherapy that otherwise would not have received systemic therapy, and the increased uptake for those eligible for chemotherapy given the access to an ICI and the additional benefit that would be anticipated from combination immunotherapy.
- 2.13. The Committee noted that assessment of patient numbers is dependent on the scenario of funding (ie lines of treatment funded, with testing considerations) but considered it reasonable to assume that if a first line ICI treatment were listed for advanced NSCLC, (as well as providing access to patients needing second-line treatment), all new eligible patients would receive an ICI in the first line setting and the second-line market would be restricted to prevalent patients only, with this patient population diminishing over a relatively short period of time (within the first year of listing). The Committee considered that this second line 'bolus' would likely consist of approximately 800 people and that similar assumptions around uptake could be expected.
- 2.14. The Committee noted its prior consideration that it would be appropriate to limit the total duration for a course of PD-L1 treatment for locally advanced and metastatic NSCLC to a maximum of two years continuous treatment, unless treatment progression was identified prior to this. The Committee noted that the duration of treatment was variable across the clinical trials, with treatment limited to up to two years in KEYNOTE 024 and KEYNOTE 110, and treatment enabled until progression (or beyond if clinical benefit in IMPower 110, OAK, and Checkmate 057), where the proportion of patients still on active treatment after two years ranged from 23% to 33%. The Committee noted that consideration of duration of treatment is medically complex, and emotionally fraught for patients, however noted that both Australia and the United Kingdom stipulate a maximum treatment duration of up to two years of treatment with ICIs with uncertainty regarding whether this could be challenged upon progression. The Committee considered that alignment with these countries would be appropriate, but that this could be reconsidered if more evidence were to become available regarding optimal treatment duration for these agents.
- 2.15. The Committee noted that exploratory data from CheckMate 153 ([Waterhouse et al. J Clin Oncol. 2020;38:3863-73](#)) compared continuous nivolumab treatment versus 1-year fixed duration in patients without progression. The Committee noted that continuous treatment prolonged progression free survival but had no statistically significant impact on overall survival (HR 0.42 [95% CI 0.25-0.71] and 0.63 [95% CI 0.33-1.20] for progression free survival and overall survival, respectively) noting that this result appeared durable and was regardless of best response achieved by the patient.
- 2.15.1. The Committee noted that while a prolonged treatment course of over 2-years does not seem to increase the rate of clinical toxicity experienced, it would however, lengthen the timeframe that an individual patient would be at risk of developing such toxicity.

- 2.16. The Committee noted a cross-trial comparison comparing two years of nivolumab treatment with treatment until progression ([Gettinger et al. J Clin Oncol. 2018;36:1675-84](#)). The Committee noted that overall survival was similar for both cohorts as noted by overall survival at two years and at three years (17% vs. 18%). The Committee noted that this was consistent with comparisons of [KEYNOTE-001](#) (two years of treatment with pembrolizumab) and [KEYNOTE-010](#) (treatment with pembrolizumab until progression), where overall survival did not differ significantly between the two groups (21% vs 23%). The Committee noted however, that the numbers of patients who remain on study at these late time points are small.
- 2.17. The Committee noted that the rate of relapse for patients who stop treatment at two years is roughly similar to those who continue treatment until progression, although those treated with ICI until disease progression usually have a longer overall survival. The Committee considered that there is a clinical concern for patients who relapse following a limited duration for treatment of two years, as the data suggests that around a third of these patients have disease that cannot be 'rescued' with re-treatment at disease progression. The Committee noted that 34 patients in Checkmate 153 who stopped treatment after one year were retreated at disease progression, and that a clinical benefit was seen in 59-65% of this patient population. The Committee also noted that in KEYNOTE 010, 79 patients stopped ICI treatment after 2 years, 25 of whom relapsed within the follow-up period. The Committee noted that 14 of these 25 were able to be re-treated, with a clinical benefit seen in 11 patients (79%). The Committee considered that on this basis, it may be clinically reasonable to permit a 3-month rechallenge upon progression, if the initial treatment duration is limited to 2 years. The Committee considered that it would be appropriate to consider this in more detail should widened access be requested and noted that there was limited evidence to guide how long patients would stay on ICI treatment if rechallenge is effective in eliciting a response.
- 2.18. The Committee noted that the overall survival curves in the clinical trials [KEYNOTE-042](#) (versus chemotherapy) and [KEYNOTE-010](#) (versus docetaxel) run parallel to each other instead of converging. The Committee considered that the reason for the parallel survival curves was unclear, and that it would suggest a lack of any treatment waning effect, which may be because very late survivors of chemotherapy are surviving because of some intrinsic immune mediated response that has been generated by the chemotherapy they have received.
- 2.19. The Committee noted that the proportion of patients treated with 3-weekly versus 6-weekly dosing is unknown, and that this would depend on pressures on day-units/infusion services, or if the patients live rurally. The Committee noted that it is likely that clinicians would have a 6-9 month cut-off with dosing 3-weekly to ensure patients will respond and are not experiencing significant toxicities. The Committee considered that then patients may be moved to 6-weekly dosing. The Committee noted, however, that there is no evidence to underpin these assumptions.
- 2.19.1. The Committee considered that weight-based dosing would be clinically appropriate for pembrolizumab and nivolumab and is consistent with prior listing of these agents in other tumour types. The Committee noted the Medsafe datasheet includes flat dosing regimens for pembrolizumab and for nivolumab. The Committee noted that dosing for atezolizumab is only for flat dosing. The Committee noted that resource constraints in pharmacies preparing these agents are significant, and that flat dosing (with the available vial sizes) may be helpful.

- 2.20. The Committee considered that the health sector costs presented by Pharmac staff were appropriate and considered the health resource utilisation reported in the PIVOTAL study ([Lee et al. BMC Health Services Research. 2018.](#)) to be broadly representative of health care utilisation in New Zealand but noted that this publication predicated the availability of ICI therapies. The Committee considered that funding of ICIs in New Zealand would likely lead to a delay in the intensity of palliative care resource utilised, and that currently most stage IV NSCLC patients are referred to palliative care at diagnosis, based on the evidence that this will improve overall survival.
- 2.20.1. The Committee considered that it was reasonable not to consider adverse event costs in economic modelling noting the resultant cost compared to the cost of the PD-L1 treatment is considered negligible. The Committee considered that a very small proportion of patients may experience long-term severe side effects that are not seen in the literature, given the limited overall survival in this patient population.
- 2.21. The Committee considered the following scenarios for PD-L1 testing, noting that currently PD-L1 testing is not funded or accessible to all patients:
- 2.21.1. If an ICI were funded for first-line monotherapy for patients with PD-L1 expression >50%, the Committee considered that all newly diagnosed locally advanced /stage IV patients who were well enough for treatment would be tested at diagnosis to avoid treatment delays. The Committee considered that this would not be expected to change if there was access to an ICI for all patients in combination with chemotherapy. If an ICI was funded for first line use with no PD-L1 expression specified, the Committee considered it likely that testing may be pursued for patients whose performance status is considered borderline for immunotherapy in order to justify use without concomitant chemotherapy and considered this could be up to 10-20% of patients.
- 2.22. The Committee noted that a requirement for PD-L1 testing would have a budgetary impact. The Committee considered that although current standard of care requires biopsies for all patients, there may be an increase in the number of biopsies an individual patient may need to undergo in order to extract enough tissue for testing. The Committee also noted again that the patients who may benefit the most from monotherapy are those with comorbidities, a subgroup likely overrepresented by patients who are Māori or Pacific, or in other populations experiencing disparities. The Committee considered that PD-L1 testing, to identify those likely to benefit from monotherapy, would be of particular benefit to this subgroup of patients.
- 2.22.1. The Committee noted that in Australia, the PBAC recommended atezolizumab in the first line be funded agnostic of PD-L1 status for both monotherapy and combination therapy (with chemotherapy and bevacizumab). The Committee noted that the PBAC also recommended funding of pembrolizumab in the first line but specified that PD-L1 >50% should be necessary for monotherapy. The Committee also noted that the PBAC recommended nivolumab and atezolizumab (but not pembrolizumab) be funded agnostic of PD-L1 status in the second line.
- 2.22.2. The Committee noted that the NICE (United Kingdom) recommended funding of atezolizumab monotherapy in first line only for those with a PD-L1 status of >50%, and that atezolizumab combination therapy was recommended those with 0-49% PD-L1 expression. The Committee noted that the NICE recommended that pembrolizumab be funded in the first line for those with a

PD-L1 expression over 50%, and PD-L1 agnostic in the second line. The Committee also noted that the NICE recommended funding of nivolumab, pembrolizumab, and atezolizumab in the second line, agnostic of PD-L1 status.

- 2.22.3. Overall, the Committee considered that PD-L1 testing would likely become reflex at diagnosis over time, to avoid treatment delays. The Committee noted the use of PD-L1 testing in other countries, where most use of ICIs in the treatment of NSCLC utilised PD-L1 testing as a means to limit treatment to PD-L1 >50%, or to inform the use of various agents and target therapy to the group with the highest possibility of benefit.
- 2.22.4. The Committee considered that if ICIs were funded for first line use with no requirement for PD-L1 testing, that most patients with poor performance status who are considered unfit for chemotherapy would likely receive an ICI as monotherapy. The Committee considered that there would remain a group of patients who would not be offered treatment at all based on presence of very high burden of disease at presentation or with poor performance status. The Committee considered that if an ICI was funded for first line use with no PD-L1 expression specified, the Committee considered it likely that testing would be pursued for most patients in order to justify use without concomitant chemotherapy.
- 2.22.5. The Committee noted the sub-group analysis of the patient population with PD-L1 1-49% in KEYNOTE 024 indicated minimal benefit from ICI therapy and the benefit seen in the PD-L1 >1% group was skewed by the significant benefit seen from the PD-L1 >50% patient cohort. The Committee considered that access to PD-L1 testing ensures selection of the patient group for first line monotherapy and would be important to enable avoidance of the morbidity of chemotherapy (in combination with immunotherapy). The Committee considered testing should be mandated in this line of therapy in order to access monotherapy. The Committee considered access without confirmation of PD-L1 expression in this patient population may result in a proportion of patients receiving futile therapy with significant cost to the sector noting the patient group most likely to receive monotherapy are those who are unable to receive combination therapy with chemotherapy.
- 2.22.6. The Committee considered there is high variability in access to PD-L1 testing, which is partly impacted by the fiscal arrangement within DHB's and how this interacts with national laboratory programmes.
- 2.22.7. The Committee considered that in any scenario, there are likely to be patients where the amount of tissue obtained from biopsy is insufficient to enable testing, or cannot be undertaken, and considered that a route to ICI therapy should be considered for these patients to avoid the need of multiple biopsies. The Committee considered access to ICIs in 1L combination therapy and 2L therapy without PD-L1 testing would reasonably accommodate for this and reduce the impact on lab testing for PD-L1 testing upon listing of any agent, giving time to develop the systems required to support reflex PD-L1 testing within New Zealand.
- 2.23. The Committee considered that the proportion of patients accessing ICI therapy as a second-line treatment option over the longer term (in the event that access was enabled in first line also, following uptake of the prevalent patient population) would reduce to a small cohort of patients whose disease has relapsed following treatment with a non-ICI agent in the first line. The Committee considered that these patients

are likely to be those with concomitant significant autoimmune conditions, where there could be concern regarding the impact ICI therapy would have on an underlying autoimmune disorder. However, the Committee considered that as use of ICI's increase, confidence regarding their use would likely increase also leading to greater proportion of clinicians recommending use in the first line.

- 2.24. The Committee considered that funding of ICIs would have a significant impact on infusion service capacity and that the funding of an ICI would require an "all of sector," multi-agency response. The Committee considered that conversations with Health NZ and Te Aho o Te Kahu would be important in facilitating access to testing and treatment to equitably address this significant unmet need in New Zealand.