ANNEX B - IMPACT OF THE CANCER DRUGS FUND (CDF) IN IMPROVING CANCER SURVIVAL

Since the reforms to the CDF in 2016, NICE has been required to evaluate all new cancer medicines. The CDF has provided funding for 234 indications, with 85,400 patients benefitting from earlier access to inovative new medicines. 53 indications have benefitted from managed access in the CDF, whilst further data is collected, with 27 currently in the fund, 26 having exited the CDF. Of those 26 indications to exit the CDF 22 (85%) have been recommended for routine commissioning. The rate of new cancer medicines entering the market remains high, in the next year 56 different cancer treatments are scheduled in the NICE work programme. Uptake of new treatments, funded via the CDF is rapid. Regular analysis of Blueteq data shows nearly all new treatments reach steady state uptake after only three months.

Funding via the CDF has supported improved outcomes for patients across many cancer indications:

- Patients with renal cell cancer have benefits from early access to immunotherapy (IO), with nivolumab plus ipilumumab (TA780) successfully exiting the CDF and avelumab with axitinib (TA645) in the CDF for a period of managed access. Both options have improved progression free survival (PFS) compared with targeted therapies alone of at least 7 months[1] and potentially much higher[2].

- Rare cancers with high unmet need have benefitted from the CDF, e.g avelumab in metastatic Merkel cell carcinoma (TA691) with an overall survival (OS) of up to 20 months in an otherwise aggressive and hard to treat disease.[3] Other rarer cancer to benefit from new treatment in the CDF are uterine cancers with microsatellite instability or mismatch repair deficiency who have access to dostarlimab (TA779), myelofibrosis patients who have access to fedratinib (TA756) and patients with squamous cell skin cancer after cemiplimab (TA802), which have now all successful exited the CDF and gone into routine commissioning.

- A number of new treatment options have been made available for triple negative breast cancer (TNBC). This has been a hard to treat cancer with limited effective treatment options. Estimated survival for patients with advanced disease was only 12 to 18 months. In 2020 patients gained early access to IO with atezolizumab (TA639) which was followed by pembrolizumab (TA801) in 2022. Pembrolizumab increased survival by 6 months (23.0 vs 16.1).[4] In July 2022 second line sacituzumab govitecan, was approved providing an effective option following IO and further extending survival by 6 months (12.1 vs 6.7)[5.] In November 2022 neoadjuvant pembrolizumab became available through interim CDF funding for patients with early TNBC; offering a 37% reduction in event-free survival (EFS)[6] events, meaning a third of women treated will avoid relapse.

- Multiple myeloma is a blood cancer that has seen the greatest number of innovative therapies launched in recent years, many of which have been introduced via managed access in the CDF. The CDF has allowed access to key triplet combinations all of which further extend survival e.g. second line daratumumab, bortezomib, dexamethasone (TA573), third line ixazomib lenalidomide dexamethasone (TA505) and fourth line satuximab with pomalidomide and dexamethasone (TA658). The cumulative effect of these new treatment is many patients now live much longer than the previous average survival of 5 years.

- Clinical understanding of non-small-cell lung cancer (NSCLC) has advanced rapidly in recent years with the identification of many new genomic mutations that can now be targeted. There are targeted therapies for 8 different mutations; EGFR; EGFR Exon 20; ALK; ROS1; RET; NTRK; KRAS G12c and METex14. The CDF has funded many new

treatments that can extend lives and are better tolerated than traditional chemotherapy. As recently as 16th November 2022, mobercertinib became the latest targeted therapy funded through interim funding from the CDF. Mobercertinib has median OS of 24 months[7]. Data collection via CDF managed access allowed osimertinib (TA416) to prove its value as a second line therapy and encouraged the company to renegotiate access for 1st line treatment in advanced disease after an initial negative recommendation from NICE (TA621 & TA654) – meaning improved access for patients and better value for money for taxpayers. First line osimertinib improves OS by 7 months (38.6 versus 31.8)[8]. Osimertinib is currently being evaluated in the CDF for early disease as an adjuvant therapy (TA761).

- Other examples of a novel targeted therapy in NSCLC are selpercatinib (TA760), targeting the rare RET mutation (1-2% of NSCLC), crizotinib for ROS1 mutations (TA529) and Sotorasib for KRAS G12C mutations (TA781). Without the 2016 reforms to the CDF all of these treatments would have received a NICE no and therefore would not have been available to patients via the NHS in England.

- The CDF has been key in establishing first line treatment of NSCLC with IO, which has been transformative for large number of patients unsuitable for targeted therapies. Of the three key 1st line pembrolizumab indications, two (TA638 & TA770) were approved after managed access in the CDF. 1st line IO improves median OS by 6 to 12 months[9,10] with a small proportion of patients having longer term benefit. Approximately 4,500 patients per year receive 1st line IO with pembrolizumab or atezolizumab (TA584 & TA705).

- Adjuvant and neoadjuvant treatments given to early-stage solid tumours after surgery increase the number of patients cured. The CDF has enabled early access to several important adjuvant therapies in the last 12 months. Adjuvant atezolizumab in NSCLC (TA823) reduces the relative risk of experiencing disease recurrence or death by 57%.[11] Abemaciclib in early breast cancer (TA810) increased disease-free survival rates from 92.2% versus 88.7%, and whilst this may sound modest, as large numbers of patients will be treated with this oral therapy, it will mean hundreds of additional women avoid their cancer returning[12].

- Ovarian cancer patients have improved survival due to the availability of oral PARP inhibitors used as maintenance therapy after either 1st or 2nd line chemotherapy e.g rucaparib (TA611) and olaparib, either alone (TA598 & TA620) or in combination with bevacizumab (TA693). Historically, the prognosis for patients with advanced ovarian cancer was very poor, PARP inhibitors have increased the proportion of people with long-term survival[13]

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