

Drug	Indication	TGA Marketing Authorization Date	Number of approvals for SAS category B applications between the 1 January 2012 - 31 July 2017
Tagrisso (osimertinib mesylate)	Treatment of adult patients with locally advanced or metastatic EGFR T790M mutation-positive NSCLC	03/08/2016	0
Xalkori (crizotinib)	Treatment of adults with previously treated ALK-positive advanced NSCL	27/09/2013	1
Zykadia (ceritinib)	Treatment of adult patients with ALK-positive locally advanced or metastatic NSCLC previously treated with crizotinib	31/03/2016	2
Giotrif (afatinib)	As monotherapy for the treatment of EGFR TKI-naïve adult patients with locally advanced or metastatic NSCLC with activating EGFR mutation(s)	07/11/2013	1
Keytruda (pembrolizumab)	As monotherapy for the treatment of locally advanced or metastatic NSCLC in adults whose tumours express PD-L1 with a $\geq 1\%$ TPS and who have received at least one prior chemotherapy regimen. Patients with EGFR or ALK positive tumour mutations should also have received targeted therapy before receiving KEYTRUDA	07/03/2017	0
Opdivo (nivolumab)	Opdivo is indicated for the treatment of locally advanced or metastatic squamous NSCLC after prior chemotherapy in adults	17/01/2016	0
Keytruda (pembrolizumab)	As monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults	16/04/2015	2
Opdivo (nivolumab)	OPDIVO as monotherapy or in combination with ipilimumab is indicated for the treatment of advanced (unresectable or metastatic) melanoma in adults.	11/01/2016	2
Zelboraf (vemurafenib)	As monotherapy for the treatment of adult patients with BRAF-V600-mutation-positive unresectable or metastatic melanoma.	10/05/2012	0
Keytruda (pembrolizumab)	Treatment of adult and pediatric patients with refractory classical Hodgkin lymphoma (cHL), or who have relapsed after three or more prior lines of therapy.	07/09/2017	0
Opdivo (nivolumab)	Treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL) after autologous stem cell transplant (ASCT) and treatment with brentuximab vedotin.	30/05/2017	0
Adcetris (brentuximab)	ADCETRIS is indicated for the treatment of adult patients with relapsed or refractory CD30+ Hodgkin lymphoma (HL), a) following autologous stem cell transplant (ASCT) or b) following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option. ADCETRIS is also indicated for the treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma (sALCL).	19/12/2013	1
Imbruvica (ibrutinib)	IMBRUVICA as a single agent is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL).	20/04/2015	1

Imbruvica (ibrutinib)	IMBRUVICA as a single agent or in combination with bendamustine and rituximab (BR) is indicated for the treatment of adult patients with CLL who have received at least one prior therapy.	20/04/2015	4
Imbruvica (ibrutinib)	IMBRUVICA as a single agent is indicated for the treatment of adult patients with Waldenström's macroglobulinaemia (WM) who have received at least one prior therapy, or in first line treatment for patients unsuitable for chemo-immunotherapy.	20/04/2015	0
Xalkori (crizotinib)	First-line treatment of adults with ALK-positive advanced NSCLC	27/09/2013	0
Xalkori (crizotinib)	Treatment of adults with ROS1-positive advanced NSCLC	13/12/2017	0
Giotrif (afatinib)	As monotherapy for the treatment of locally advanced or metastatic NSCLC of squamous histology progressing on or after platinum-based chemotherapy	07/11/2013	0
Keytruda (pembrolizumab)	As monotherapy for the first-line treatment of metastatic NSCLC in adults whose tumours express PD-L1 with a $\geq 50\%$ TPS with no EGFR or ALK positive tumour mutations	06/03/2017	0
Keytruda (pembrolizumab)	First-Line Combination Therapy with Pemetrexed and Carboplatin for Patients with Metastatic Nonsquamous NSCLC, Irrespective of PD-L1 Expression	16/04/2015	0
Yervoy (ipilimumab)	Yervoy is indicated for the treatment of advanced (unresectable or metastatic) melanoma in adults	04/07/2011	0
Mekinist (trametinib)	As monotherapy or in combination with dabrafenib is indicated for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. Trametinib monotherapy has not demonstrated clinical activity in patients who have progressed on a prior BRAF inhibitor therapy.	14/02/2014	1
Tafinlar (dabrafenib)	Dabrafenib as monotherapy or in combination with trametinib is indicated for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation.	27/08/2013	0
Zydelig (idelalisib)	In combination with an antiCD20 monoclonal antibody (rituximab or ofatumumab) for the treatment of adult patients with chronic lymphocytic leukaemia (CLL): who have received at least one prior therapy, or as first line treatment in the presence of 17pdeletion or TP53mutation in patients who are not eligible for any other therapies	09/02/2015	0
Zydelig (idelalisib)	As monotherapy for the treatment of adult patients with follicular lymphoma (FL) that is refractory to two prior lines of treatment	09/02/2015	0
Bosulif (bosutinib)	Bosulif is indicated for the treatment of adult patients with chronic phase (CP), accelerated phase (AP), and blast phase (BP) Philadelphia chromosome positive (Ph+ CML) previously treated with one or more tyrosine kinase inhibitor(s) and for whom imatinib, nilotinib and dasatinib are not considered appropriate	29/04/2014	0

	treatment options		
Arzerra (ofatumumab)	<p>Previously untreated CLL: Arzerra in combination with chlorambucil or bendamustine is indicated for the treatment of patients with CLL who have not received prior therapy and who are not eligible for fludarabine-based therapy.</p> <p>Relapsed CLL: Arzerra is indicated in combination with fludarabine and cyclophosphamide for the treatment of adult patients with relapsed CLL.</p> <p>Refractory CLL: Arzerra is indicated for the treatment of CLL in patients who are refractory to fludarabine and alemtuzumab</p>	11/02/2013	0
Iclusig (ponatinib)	<p>1. In adult patients with chronic phase, accelerated phase, or blast phase chronic myeloid leukaemia (CML) who are resistant to dasatinib or nilotinib; who are intolerant to dasatinib or nilotinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation</p> <p>2. In adult patients with Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) who are resistant to dasatinib; who are intolerant to dasatinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation</p>	26/11/2014	7