

The Utilization of the Accelerated Approval Pathway in Oncology: A Case Study of Pembrolizumab

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Supplementary Table: Other Anti-PD-(L)1 Granted Accelerated Approval by the US FDA

Anti-PD-(L)1	First approval (Y/N)	AA Approval Date	AA indication	Status
nivolumab	Y	12/22/2014	Unresectable or metastatic melanoma and progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor	verified clinical benefit
nivolumab	N	9/30/2015	In combination with ipilimumab for BRAF V600 wild-type unresectable or metastatic melanoma	verified clinical benefit
nivolumab	N	1/23/2016	1) In combination with ipilimumab for unresectable or metastatic melanoma to remove the restriction for treatment of only patients with BRAF wild-type melanoma; 2) As a single agent for BRAF V600 mutation positive unresectable or metastatic melanoma to remove the restriction that such patients should have disease progression following ipilimumab and a BRAF inhibitor	verified clinical benefit
nivolumab	N	5/17/2016	For the treatment of classical Hodgkin Lymphoma that has relapsed or progressed after autologous hematopoietic stem cell transplantation (HSCT) and post-transplantation brentuximab vedotin.	ongoing
atezolizumab	Y	5/18/2016	Locally advanced or metastatic urothelial carcinoma that progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy	withdrawn
nivolumab	N	2/2/2017	Locally advanced or metastatic urothelial carcinoma that: • progressed during or following platinum-containing chemotherapy • progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy	verified clinical benefit
avelumab	Y	3/23/2017	Treatment of adults and pediatrics patients 12 years and older with metastatic merkel cell carcinoma (MCC)	verified clinical benefit
atezolizumab	N	4/17/2017	Patients with locally advanced or metastatic urothelial carcinoma (mUC) who are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 as determined by an FDA approved test or who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status	withdrawn

nivolumab	N	4/25/2017	Treatment of adult patients with classical Hodgkin lymphoma that has relapsed or progressed after: - Autologous hematopoietic stem cell transplantation (HSCT) and brentuximab vedotin, Or - 3 or more lines of systemic therapy that includes autologous HSCT	ongoing
durvalumab	Y	5/1/2017	Locally advanced or metastatic urothelial carcinoma that progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy	withdrawn
avelumab	N	5/9/2017	Locally advanced or metastatic urothelial carcinoma following disease progression on platinum-containing chemotherapy or disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy	verified clinical benefit
nivolumab	N	7/31/2017	For the treatment of adult and pediatric patients 12 years and older with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (CRC) that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan	ongoing
nivolumab	N	9/22/2017	Hepatocellular carcinoma previously treated with sorafenib	withdrawn
nivolumab	N	7/10/2018	In combination with ipilimumab, is indicated for the treatment of adults and pediatric patients 12 years and older with microsatellite instability-high (MSI-H) or DNA mismatch repair deficient (dMMR), metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan	ongoing
nivolumab	N	8/16/2018	Metastatic SCLC with progression after platinum-based chemotherapy and at least one other line of therapy	withdrawn
atezolizumab	N	3/8/2019	In combination with paclitaxel protein-bound for unresectable locally advanced or metastatic triple-negative breast cancer whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells of any intensity covering = 1% of the tumor area), as determined by an FDA-approved test	withdrawn
nivolumab	N	3/10/2020	In combination with ipilimumab, for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib	ongoing
cemiplimab-rwlc	N	2/9/2021	Patients with metastatic basal cell carcinoma (mBCC) previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate	verified clinical benefit

dostarlimab-gxly	Y	4/22/2021	Adult patients with mismatch repair deficient (dMMR) recurrent or advanced endometrial cancer (EC), as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum-containing regimen	verified clinical benefit
dostarlimab-gxly	N	8/17/2021	Treatment for adult patients with mismatch repair deficient (dMMR) recurrent or advanced solid tumors, as determined by an FDA-approved test, that have progressed on or following prior treatment and who have no satisfactory alternative treatment options	ongoing
retifanlimab-dlwr	Y	3/22/2023	Adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC)	ongoing