

T A B L E 2 . OHOP Approvals From January 1, 2014, to May 18, 2015 (excluding 1 biosimilar)

APPROVAL DATE	TYPE	DRUG	PRIMARY TARGET	INDICATION	CDx
April 24, 2015	T	Ramucirumab	VEGF-R2	In combination with FOLFIRI for the treatment of patients with metastatic colorectal cancer whose disease has progressed on a first-line bevacizumab-, oxaliplatin-, and fluoropyrimidine-containing regimen.	No
March 10, 2015	T	Dinutuximab	GD2	In combination with granulocyte-macrophage colony-stimulating factor, interleukin-2, and 13-cis-retinoic acid, for the treatment of pediatric patients with high-risk neuroblastoma who achieve at least a partial response to prior first-line multi-agent multimodality therapy.	No
March 4, 2015	T	Nivolumab	PD-1	Treatment of patients with metastatic squamous non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy.	No
February 23, 2015	A	Panobinostat	HDAC	In combination with bortezomib and dexamethasone for the treatment of patients with multiple myeloma who have received at least 2 prior regimens, including bortezomib and an immunomodulatory agent.	No
February 13, 2015	T	Lenvatinib	VEGF	Treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer.	No
February 3, 2015	A	Palbociclib	CDK4/6	In combination with letrozole for the treatment of postmenopausal women with estrogen receptor-positive, human epidermal growth factor receptor 2-negative advanced breast cancer as initial endocrine-based therapy for their metastatic disease.	No
January 29, 2015	T	Ibrutinib	BTK	Treatment of patients with Waldenström's macroglobulinemia.	No
December 22, 2014	A	Nivolumab	PD-1	Treatment of patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if <i>BRAF V600</i> mutation-positive, a BRAF inhibitor.	No
December 19, 2014	T	Olaparib	PARP	Treatment of patients with deleterious or suspected deleterious germline BRCA mutated (as detected by an FDA-approved test) advanced ovarian cancer who have been treated with 3 or more prior lines of chemotherapy.	Yes
December 16, 2014	T	Lanreotide	N/A	Treatment of patients with unresectable, well or moderately differentiated, locally advanced, or metastatic gastroenteropancreatic neuroendocrine tumors, to improve progression free survival.	No
December 12, 2014	T	Ramucirumab	VEGF-R2	In combination with docetaxel for the treatment of patients with metastatic NSCLC with disease progression on or after platinum-based chemotherapy.	No
December 4, 2014	T	Ruxolitinib	JAK1/2	Treatment of patients with polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea.	No
November 14, 2014	T	Bevacizumab	VEGF	In combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan for the treatment of patients with platinum-resistant, recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.	No
November 5, 2014	T	Ramucirumab	VEGF-R2	In combination with paclitaxel for the treatment of patients with advanced gastric or gastroesophageal junction (GEJ) adenocarcinoma.	No
September 4, 2014	A	Pembrolizumab	PD-1	Treatment of patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if <i>BRAF V600</i> mutation-positive, a BRAF inhibitor.	No
August 14, 2014	T	Bevacizumab	VEGF	Treatment of persistent, recurrent, or metastatic cervical cancer, in combination with paclitaxel and cisplatin or paclitaxel and topotecan.	No
July 23, 2014	T	Idelalisib	PI3K δ	Treatment of patients with relapsed chronic lymphocytic leukemia (CLL), in combination with rituximab, for whom rituximab alone would be considered appropriate therapy due to other comorbidities.	No
July 3, 2014	A	Belinostat	HDAC	Treatment of patients with relapsed or refractory peripheral T-cell lymphoma.	No
April 29, 2014	T	Ceritinib	ALK	Treatment of patients with ALK-positive metastatic NSCLC with disease progression on, or who are intolerant to, crizotinib.	No
April 28, 2014	T	Mercaptopurine	N/A	Treatment of patients with acute lymphoblastic leukemia as part of a combination regimen.	No
April 23, 2014	T	Siltuximab	IL-6	Multicentric Castleman's disease who are human immunodeficiency virus-negative and human herpes virus-8-negative.	No
April 21, 2014	T	Ramucirumab	VEGF-R2	Advanced or metastatic, gastric, or GEJ adenocarcinoma with disease progression on or after prior treatment with fluoropyrimidine- or platinum-containing chemotherapy.	No
April 17, 2014	T	Ofatumumab	CD20	In combination with chlorambucil, for the treatment of previously untreated patients with CLL for whom fludarabine-based therapy is considered inappropriate.	No
February 12, 2014	T	Ibrutinib	BTK	Patients with CLL who have received at least 1 prior therapy.	No
January 10, 2014	A	Trametinib/ dabrafenib	MEK/BRAF	Patients with unresectable or metastatic melanoma with a <i>BRAF V600E</i> or <i>V600K</i> mutation as detected by an FDA-approved test.	Yes

A indicates accelerated approval; CDx, companion diagnostic; OHOP, Office of Hematology and Oncology Products; T, traditional (regular) approval.