Review of NICE, PBAC, and CDA HTA Outcomes For Oncology Drugs Approved by the FDA Through Project Orbis (2022-2023)

Bodke A; Dutton CA; Tang M. Nexus Values, United Kingdom

Supplementary material

Table 1: Drug-indications approved by the FDA through Project Orbis in 2022-2023 with final guidance in HTA by NICE, PBAC, and CDA

Drug	FDA approval	NICE			PBAC		CDA		
		Ref ID	Date guidance published	Title	Date guidance published	Title	Ref ID	Date guidance published	Title
Dostarlimab-gxly	Dostarlimab-gxly (Jemperli, GlaxoSmithKline) with carboplatin and paclitaxel, followed by single-agent dostarlimab-gxly, for primary advanced or recurrent endometrial cancer (EC) that is mismatch repair deficient (dMMR), as determined by an FDA-approved test, or microsatellite instability-high (MSI-H)	TA963	03 April 2024	Dostarlimab with platinum-based chemotherapy for treating advanced or recurrent endometrial cancer with MSI-H or dMMR	November 2023	Dostarlimab in combination with platinum containing chemotherapy (DOS+CP), for the treatment of primary advanced or first recurrent endometrial cancer that is mismatch repair deficient dMMR	PC0325-000	22 May 2024	Jemperli (dostarlimab for injection combination with carboplatin and paclitaxel for adult patients with primary advanced or recurrent dMMR / MSI-H endometrial cancer who are candidates for systemic therapy

Drug	FDA approval	NICE			PBAC		CDA		
		Ref ID	Date guidance published	Title	Date guidance published	Title	Ref ID	Date guidance published	Title
Elranatamab	Granted accelerated approval to elranatamab-bcmm (Elrexfio, Pfizer, Inc.), a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager, for adults with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody	TA1023	11 December 2024	Elranatamab for treating relapsed and refractory multiple myeloma after 3 or more treatments	November 2023	Elranatamab for the treatment of adult patients with relapsed/refractory multiple myeloma (RRMM) who have received at least 3 prior therapies including a proteasome inhibitor (PI), an immunomodulatory drug (IMiD) and an anti-CD38 monoclonal antibody (mAb)	PC0315-000	18 June 2024	For the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 3 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy

Drug	FDA approval	NICE			PBAC		CDA		
		Ref ID	Date guidance published	Title	Date guidance published	Title	Ref ID	Date guidance published	Title
Belzutifan	Belzutifan (Welireg, Merck), a hypoxia-inducible factor inhibitor for adult patients with von Hippel-Lindau (VHL) disease who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastoma, or pancreatic neuroendocrine tumors (pNET), not requiring immediate surgery	TA1011	16 October 2024	Belzutifan for treating tumours associated with VHL	July 2024	Belzutifan the treatment of patients with von Hippel-Lindau (VHL) disease who require therapy for associated renal cell carcinoma (RCC), central nervous system haemangioblastomas (CNS Hb), or pancreatic neuroendocrine tumours (pNET), not requiring immediate surgery	PC0309-000	20 September 2023	Belzutifan for the treatment of adult patients with VHL disease who require therapy for associated non-metastatic RCC, CNS, hemangioblastomas, and pNET, not requiring immediate surgery
Nivolumab	The FDA approved nivolumab (Opdivo, Bristol-Myers Squibb Company) with platinum-doublet chemotherapy for adult patients with resectable non-small cell lung cancer (NSCLC) in the neoadjuvant setting.	TA876	22 March 2023	Nivolumab with chemotherapy for neoadjuvant treatment of resectable NSCLC	March 2023	Nivolumab in combination with chemotherapy for the neoadjuvant treatment of patients with resectable non-small cell lung cancer (NSCLC)	PC0303-000	18 April 2023	Neoadjuvant treatment of adult patients with resectable NSCLC (tumours ≥4cm or node positive) when used in combination with platinum-doublet chemotherapy

Drug	FDA approval	NICE			PBAC		CDA		
		Ref ID	Date guidance published	Title	Date guidance published	Title	Ref ID	Date guidance published	Title
Olaparib	The FDA approved Olaparib (Lynparza, AstraZeneca Pharmaceuticals, LP) for the adjuvant treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) human epidermal growth factor receptor 2 (HER2)-negative high-risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy. Patients must be selected for therapy based on an FDA-approved companion diagnostic for olaparib	TA886	10 May 2023	Olaparib for adjuvant treatment of BRCA mutation-positive HER2-negative high-risk early breast cancer after chemotherapy	November 2023	Olaparib g for patients with human epidermal growth factor receptor 2 negative (HER2-) high risk early breast cancer (eBC) with a confirmed germline Breast Cancer Gene 1 (gBRCA1) or gBRCA2 mutation who have previously been treated with neoadjuvant or adjuvant chemotherapy	PC0299-000	20 March 2023	Olaparib for the adjuvant treatment of adult patients with deleterious or suspected deleterious gBRCAm, HER2-negative high risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy

Drug	FDA approval	NICE			PBAC		CDA		
		Ref ID	Date guidance published	Title	Date guidance published	Title	Ref ID	Date guidance published	Title
Fam-trastuzumab deruxtecan-nxki	The FDA approved fam-trastuzumab deruxtecan-nxki (Enhertu, Daiichi Sankyo, Inc.) for adult patients with unresectable or metastatic HER2-positive breast cancer who have received a prior anti-HER2-based regimen either in the metastatic setting, or in the neoadjuvant or adjuvant setting and have developed disease recurrence during or within 6 months of completing therapy	TA862	1 Feb 2023	Trastuzumab deruxtecan for treating HER2-positive unresectable or metastatic breast cancer after 1 or more anti-HER2 treatments	July 2023	Trastuzumab deruxtecan (T-DXd; Enhertu®) for the treatment of human epidermal growth factor receptor 2 (HER2) positive metastatic breast cancer (mBC) for patients who have progressed following a prior HER2 directed therapy in the metastatic setting or relapsed during or within 6 months of receiving a HER2 directed therapy in the adjuvant setting	PC0285-000	17 October 2022	Trastuzumab deruxtecan for the treatment of adult patients with unresectable or metastatic HER2 positive breast cancer who have received a prior treatment with an anti-HER2-based regimen in the metastatic setting or developed disease recurrence during or within 6 months of completing neoadjuvant or adjuvant therapy

Drug	FDA approval	NICE			PBAC		CDA		
		Ref ID	Date guidance published	Title	Date guidance published	Title	Ref ID	Date guidance published	Title
Fam-trastuzumab deruxtecan-nxki	The FDA approved fam-trastuzumab deruxtecan-nxki (Enhertu, Daiichi Sankyo, Inc.) for adult patients with unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer who have received a prior chemotherapy in the metastatic setting or developed disease recurrence during or within six months of completing adjuvant chemotherapy	TA992	29 July 2024	Trastuzumab deruxtecan for treating HER2-low metastatic or unresectable breast cancer after chemotherapy	May 2024	Trastuzumab deruxtecan (T-DXd) for the treatment of patients with human epidermal growth factor receptor 2 (HER2) low (immunohistochemical [IHC] 1+ or IHC 2+ and in situ hybridisation [ISH] negative) unresectable breast cancer and/or metastatic breast cancer	PC0305-000	18 July 2023	Trastuzumab deruxtecan for the treatment of adult patients with unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer who have received at least one prior line of chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy
Darolutamide	The FDA approved darolutamide (Nubeqa, Bayer HealthCare Pharmaceuticals Inc.) tablets in combination with docetaxel for adult patients with metastatic hormone-sensitive prostate cancer (mHSPC)	TA903	21 June 2023	Darolutamide with androgen deprivation therapy and docetaxel for treating hormone-sensitive metastatic prostate cancer	May 2023	Darolutamide for the treatment of mHSPC	PC0294-000	23 January 2023	Darolutamide for the treatment of patients with mHSPC in combination with docetaxel

Drug	FDA approval	NICE			PBAC		CDA		
		Ref ID	Date guidance published	Title	Date guidance published	Title	Ref ID	Date guidance published	Title
Durvalumab	The FDA approved durvalumab (Imfinzi, AstraZeneca UK Limited) in combination with gemcitabine and cisplatin for adult patients with locally advanced or metastatic biliary tract cancer (BTC)	TA944	10 January 2024	Durvalumab with gemcitabine and cisplatin for treating unresectable or advanced biliary tract cancer	July 2023	Durvalumab for use in combination with gemcitabine and cisplatin for the treatment of patients with locally advanced or metastatic BTC	PC0296-000	22 February 2023	Durvalumab with gemcitabine-based chemotherapy for the treatment of patients with locally advanced or metastatic BTC

Abbreviations: BCMA: B-Cell Maturation Antigen; BTC: Biliary Tract Cancer; CDA: Canadian Drug Agency; CNS: Central Nervous System; dMMR: Mismatch Repair Deficient; EC: Endometrial Cancer; eBC: Early Breast Cancer; FDA: Food and Drug Administration; gBRCA: Germline Breast Cancer Gene; gBRCAm: Germline BRCA Mutation; HER2: Human Epidermal Growth Factor Receptor 2; HTA: Health Technology Assessment; IHC: Immunohistochemistry; IMiD: Immunomodulatory Drug; ISH: In Situ Hybridization; mAb: Monoclonal Antibody; mBC: Metastatic Breast Cancer; mHSPC: Metastatic Hormone-Sensitive Prostate Cancer; MMR: Mismatch Repair; MSI-H: Microsatellite Instability-High; NICE: National Institute for Health and Care Excellence; NSCLC: Non-Small Cell Lung Cancer; PBAC: Pharmaceutical Benefits Advisory Committee; PI: Proteasome Inhibitor; pNET: Pancreatic Neuroendocrine Tumor; RCC: Renal Cell Carcinoma; RRMM: Relapsed/Refractory Multiple Myeloma; TA: Technology Appraisal; VHL: Von Hippel-Lindau.