

Policy #	Policy Name	Brief Description of Policy Change	Reason for Changes
NEW	Loqtorzi (toripalimab-tpzi)	On October 27, 2023, the Food and Drug Administration approved toripalimab-tpzi (LOQTORZ, Coherus BioSciences, Inc.) with cisplatin and gemcitabine for the first-line treatment of adults with metastatic or recurrent, locally advanced nasopharyngeal carcinoma (NPC). FDA also approved toripalimab-tpzi as a single agent for adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy.	New FDA Drug/Indication
NEW	Fruzaqla (fruquintinib)	On November 8, 2023, the Food and Drug Administration approved fruquintinib (Fruzaqla, Takeda Pharmaceuticals, Inc.) for adult patients with metastatic colorectal cancer (mCRC) who received prior fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type and medically appropriate, an anti-EGFR therapy.	New FDA Drug/Indication
UM ONC_1203	Adcetris (brentiximab)	Annual Review	Annual Review
UM ONC_1218	Provenge (sipuleucel-T)	Annual Review	Annual Review
UM ONC_1228	Xtandi (enzalutamide)	On November 16, 2023, the Food and Drug Administration approved enzalutamide (Xtandi, Astellas Pharma US, Inc.) for non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis (high-risk BCR).	New FDA Drug/Indication
UM ONC_1263	Keytruda (pembrolizumab)	On October 31, 2023, the Food and Drug Administration approved pembrolizumab (Keytruda, Merck) to be used with gemcitabine and cisplatin for locally advanced unresectable or metastatic biliary tract cancer (BTC).	New FDA Drug/Indication
UM ONC_1263	Keytruda (pembrolizumab)	On November 7, 2023, the Food and Drug Administration revised the existing indication of pembrolizumab (Keytruda, Merck) with trastuzumab, fluoropyrimidine, and platinum-containing chemotherapy for the first-line treatment of patients with locally advanced unresectable or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma. This updated indication, which remains approved under accelerated approval regulations, restricts its use to patients whose tumors express PD-L1 (CPS $\geq$ 1) as determined by an FDA-approved test.	New FDA Drug/Indication
UM ONC_1263	Keytruda (pembrolizumab)	On November 16, 2023, the Food and Drug Administration approved pembrolizumab (Keytruda, Merck) with fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of adults with locally advanced unresectable or metastatic HER2-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma.	New FDA Drug/Indication
UM ONC_1284	Ninlaro (ixazomib)	Annual Review	Annual Review
UM ONC_1301	Rubraca (rucaparib)	Annual Review	Annual Review
UM ONC_1326	Vyxeos (daunorubicin and cytarabine liposomal)	Annual Review	Annual Review
UM ONC_1340	Tibsovo (ivosidenib)	On October 24, 2023, the Food and Drug Administration approved ivosidenib (Tibsovo, Servier Pharmaceuticals LLC) for adult patients with relapsed or refractory myelodysplastic syndromes (MDS) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation, as detected by an FDA-approved test.	New FDA Drug/Indication
UM ONC_1411	Blenrep (belantamab mafodotin-blmf)	Annual Review	Annual Review
UM ONC_1442	Truseltiq (infigratinib)	Annual Review	Annual Review
UM ONC_1470	Tecvayli (teclistamab-cqyv)	Annual Review	Annual Review