Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
NEW	Vanflyta (quizartinib)	Positive	On July 20, 2023, the Food and Drug Administration approved quizartinib (Vanflyta, Daiichi Sankyo, Inc.) with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy, for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FLT3 internal tandem duplication (ITD)-positive, as detected by an FDA-approved test.	New FDA Drug/Indication
NEW	Elrexfio (elranatamab-bcmm)	Positive	On August 14, 2023, the Food and Drug Administration 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.	New FDA Drug/Indication
NEW	Talvey (talquetamab-tgvs)	Positive	On August 9, 2023, the Food and Drug Administration granted accelerated approval to talquetamab-tgvs (Talvey, Janssen Biotech, Inc.) 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.	New FDA Drug/Indication
UM ONC_1407	Trodelvy (sacituzumab govitecan-hziy)	No clinical change	Annual Review	N/A
UM ONC_1215	Treanda/Bendeka/Belrapzo (bendamustine)	No clinical change	Annual Review	N/A
UM ONC_1363	Nubeqa (darolutamide)	No clinical change	Annual Review	N/A
UM ONC_1311	Lonsurf (trifluridine/tipiracil)	Positive	On August 2, 2023, the Food and Drug Administration approved trifluridine and tipiracil (LONSURF, Taiho Oncology, Inc.) with bevacizumab, for metastatic colorectal cancer (mCRC) previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy. FDA had previously approved single-agent LONSURF for this indication in September 2015.	New FDA Drug/Indication
UM ONC_1433	Jemperli (dostarlimab-gxly)	Positive	On July 31, 2023, the Food and Drug Administration approved 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).	New FDA Drug/Indication
UM ONC_1134	Trastuzumab Products, Pertuzumab, and Phesgo	No clinical change	Review Requested (Internal)	N/A
UM ONC_1208	Zytiga or Yonsa (abiraterone acetate)	Positive	On August 11, 2023, the Food and Drug Administration approved the fixed dose combination of niraparib and abiraterone acetate (Akeega, Janssen Biotech, Inc.), with prednisone, for adult patients with deleterious or suspected deleterious BRCA-mutated castration-resistant prostate cancer (mCRPC), as determined by an FDA-approved test.	New FDA Drug/Indication
UM ONC_1263	Keytruda (pembrolizumab)	No clinical change	Annual Review	N/A
UM ONC_1307	Zejula (niraparib)	Positive	On August 11, 2023, the Food and Drug Administration approved the fixed dose combination of niraparib and abiraterone acetate (Akeega, Janssen Biotech, Inc.), with prednisone, for adult patients with deleterious or suspected deleterious BRCA-mutated castration-resistant prostate cancer (mCRPC), as determined by an FDA-approved test.	New FDA Drug/Indication
UM ONC_1381	Padcev (enfortumab vedotin-ejfv)	No clinical change	Annual Review	N/A
UM ONC _1089	Libtayo (cemiplimab-rwlc)	Positive	Review Requested (Internal)	N/A