Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
New	Jaypirca (pirtobrutinib)	N/A	N/A	N/A
New	Orserdu (elacestrant)	N/A	N/A	N/A
UM ONC_1134	Trastuzumab Products, Pertuzumab (pertuzumab), and Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf)	Positive change	Remove inclusion criteria: B.HER-2 Positive Breast Cancer ~~5.NOTE 2: For adjuvant therapy in HER-2 positive breast cancer, trastuzumab/trastuzumab biosimilar + pertuzumab containing regimen is indicated in members who did not receive neoadjuvant therapy and are node positive at surgery OR members who have received neoadjuvant therapy and did NOT have any residual disease in the breast and/or axillary lymph node at surgery. If there is evidence of residual disease in the breast and or axillary nodes at surgery, then the preferred drug per NCH Policy for adjuvant therapy is Kadcyla (ado-trastuzumab). This recommendation is based on data from the KATHERINE trial (referenced below).~~	Per NCH Pathway expansion
UM ONC_1235	Doxil (liposomal doxorubicin)	Positive change	Add inclusion criteria: D.Ovarian Cancer 1.Doxil (liposomal doxorubicin) will be used in combination with Carboplatin for platinum sensitive relapsed/recurrent ovarian cancer OR 2.As a single agent or in combination with Avastin (bevacizumab)/bevacizumab biosimilar for platinum-resistant relapsed/recurrent ovarian cancer.	Per Compendia Listing
UM ONC_1242	Jakafi (ruxolitinib)	Negative change	Add exclusion criteria: A.Disease progression while taking Jakafi (ruxolitinib) or another JAK2 inhibitor [e.g., Inrebic (fedratinib) or Vonjo (pacritinib)]. D.Treatment exceeds the maximum limit of ~~120~~60 (5 mg), 60 (10 mg), 60 (15 mg), 60 (20 mg), or 60 (25 mg) tablets/month.	Per FDA labeling
UM ONC_1261	Cyramza (ramucirumab)	No Clinical Changes	N/A	N/A
UM ONC_1262	Imbruvica (ibrutinib)	Negative change	Remove inclusion criteria: B.Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) 1.Imbruvica (ibrutinib) use as a single agent is supported for initial and subsequent therapy for all prognostic categories of CLL/SLL. ~~2.Imbruvica (ibrutinib) in combination with Venclexta (venetoclax) is supported as first line or subsequent line therapy if the member has CLL with any one of the following additional risk factors: age 65 years or older, del(17p), mutated TP53, del (11q), unmutated IGHV (Immunoglobulin Heavy Chain).~~	Per Compendia Listing NCCN 2B
UM ONC_1262	Imbruvica (ibrutinib)	Positive change	Add exclusion criteria: D.Treatment exceeds the maximum limit of 120 (140 mg) or 240 (70 mg) capsules a month; 120 (140 mg), ~~36~~0 (280 mg), 30 (420 mg), 30 (560 mg) tablets a month.	Per FDA labeling
UM ONC_1263	Keytruda (pembrolizumab)	Positive change	Add inclusion criteria: N.Non-Small Cell Lung Cancer (NSCLC) – Squamous and Non-Squamous d.As adjuvant monotherapy, up to 12 months, following complete resection and platinum-based chemotherapy for members with stage IB-IIIA NSCLC, regardless of PD-L1 status.	New FDA Indication

UM ONC_1263	Keytruda (pembrolizumab)	Negative change	Add exclusion criteria: C.Length of Keytruda (pembrolizumab) treatment is greater than 12 months for adjuvant therapy of resected Melanoma or NSCLC.	Per FDA labeling
UM ONC_1297	Venclexta (venetoclax)	Negative change	Remove inclusion criteria: E.Mantle Cell Lymphoma ~~1.Venclexta (venetoclax) may be used as a single agent or in combination with rituximab/ibrutinib for relapsed/refractory Mantle Cell Lymphoma.~~	Per NCH Pathway exclusion
UM ONC_1304	Generic Drugs	Positive change	Remove inclusion criteria: Change amifostine and dexrazoxane to tier 1. Remove Evomela from scope	Other: Per Tier policy
UM ONC_1335	Braftovi (encorafenib)	Negative change	Add inclusion criteria: B.Melanoma 1.Braftovi (encorafenib) may be used in combination with Mektovi (binimetinib) in BRAF V600E or V600K mutation positive unresectable/metastatic melanoma~~, in combination with Mektovi (binimetinib)~~and the member has an intolerance/contraindication to the use of the preferred MEK and BRAF inhibitor combination, Cotellic (cobimetinib) + Zelbroaf (vemurafenib). 2.NOTE: Per NCH Policy, Braftovi (encorafenib) + Mektovi (binimetinib) regimen is not approvable for the treatment of metastatic BRAF V600E or V600K mutation positive melanoma. The preferred oral combination is Zelboraf (vemurafenib) + Cotellic (cobimetinib), an exception could be made if the member is intolerant to or has a contraindication to the NCH Preferred combination. This recommendation is based on a lack of Level 1 evidence to show superiority of one combination of BRAF + MEK inhibitor over another. Please refer to UM ONC_1279 Cotellic (cobimetinib) or UM ONC_1207 Zelboraf (vemurafenib) policy.	Step Therapy Criteria
UM ONC_1347	Lorbrena (lorlatinib)	No Clinical Changes	N/A	N/A
UM ONC_1349	Talzenna (talazoparib)	Negative change	Add inclusion criteria: B.Breast Cancer 1.NOTE: Per NCH policy, Talzenna (talazoparib) ~~is not recommended~~ is not approvable for use when a PARP inhibitor is indicated for use in germline or somatic BRCA1/2 mutation positive metastatic breast cancer. The preferred PARP inhibitor is Lynparza (Olaparib) for the above clinical setting, unless there is an intolerance or a contraindication to Lynparza (Olaparib). This recommendation is based on data from the phase III EMBRACA trial in which Talzenna (talazoparib) did not show a statistically significant overall survival benefit for patient with metastatic breast cancer with a germline BRCA 1/2 mutation, in addition to a lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes for one PARP inhibitor over another. 2. ~~NOTE: The preferred PARP inhibitor, per NCH policy and NCH pathway, is Lynparza (olaparib) for recurrent or metastatic germline BRCA 1/2 mutation positive breast cancer. Please refer to the NCH Pathway document for the current recommended regimens.~~	Step Therapy Criteria

UM ONC_1366	Inrebic (fedratinib)	Negative change	Add inclusion criteria: B.Myelofibrosis (MF) 4.NOTE: Per NCH Policy, Inrebic (fedratinib) is not approvable for the treatment of primary myelofibrosis or secondary myelofibrosis (e.g., post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis). The preferred agent, per NCH Policy, is Jakafi (ruxolitinib) over Inrebic (fedratinib), unless there is an intolerance or a contraindication to Jakafi (ruxolitinib). This recommendation is based on the lack of level 1 evidence (randomized trial and/or meta-analyses) showing superior outcomes with Inrebic (fedratinib) over Jakafi (ruxolitinib). Please refer to UM ONC_1242 Jakafi (ruxolitinib) policy.	Step Therapy Criteria
UM ONC_1366	Inrebic (fedratinib)	Negative change	Add exclusion criteria: A.Inrebic (fedratinib) use after disease progression with the same regimen or another JAK2 inhibitor [e.g., Jakafi (ruxolitinib) or Vonjo (pacritinib)].	Per Clinical Trial Analysis/Criteria
UM ONC_1374	Balversa (erdafitinib)	Positive change	Remove inclusion criteria: B.Urothelial Carcinoma 1.The member has unresectable or metastatic urothelial carcinoma and Balversa (erdafitinib) is being used as a single agent when ALL the following criteria are met: a.Documented FGFR3 mutation or FGFR2/3 fusion in tumor tissue (using the FDA approved companion diagnostic: therascreen or another appropriate genomic test) AND b.Member has had disease progression on/intolerance to platinum-based chemotherapy AND disease progression on/intolerance to Immune Check Point Inhibitor therapy (e.g., avelumab, nivolumab, or pembrolizumab) OR c.If ineligible for platinum containing therapy, the member had disease progression on/intolerance to Immune Check Point Inhibitor therapy (e.g., atezolizumab, avelumab, nivolumab, or pembrolizumab). ~~d.NOTE: The above recommendations are based on the lack of Level 1 evidence (randomized trial and/or meta-analysis) showing superiority of Balversa (erdafetinib) over Immune Checkpoint Inhibitor therapy in the second line setting.~~	Other: formatting change
UM ONC_1395	Clolar (clofarabine)	No Clinical Changes	N/A	N/A

UM ONC_1397	Mektovi (binimetinib)	Negative change	Add inclusion criteria: B.Melanoma 1.The member has metastatic/unresectable melanoma with BRAF V600E or V600K activating mutation AND 2.Mektovi (binimetinib) will be used in combination with Braftovi (encorafenib) AND 3.The member is intolerant to/has a contraindication to the preferred combination of Cotellic (cobimetinib) + Zelboraf (vemurafenib). ~~4.NOTE: The preferred BRAF a nd MEK inhibitor combination regimen, per NCH policy and NCH pathway, for unresectable/metastatic BRAF mutation positive melanoma is the combination of Cotellic (cobimetinib) + Zelboraf (vemurafenib) over Mektovi (binimetinib) + Braftovi (encorafenib). Rationale: Lack of Level 1 evidence (randomized trial and/or meta-analysis) showing superior outcomes with Mektovi (binimetinib) + Braftovi (encorafenib) over Cotellic (cobimetinib) + Zelboraf (vemurafenib).~~ 4.NOTE: Per NCH Policy, Mektovi (binimetinib) + Braftovi (encorafenib) regimen is not approvable for the treatment of metastatic BRAF V600E or V600K mutation positive melanoma. The preferred oral combination is Cotellic (cobimetinib) + Zelboraf (vemurafenib), an exception could be made if the member is intolerant to or has a contraindication to the NCH Preferred combination. This recommendation is based on a lack of Level 1 evidence to show superiority of one combination of BRAF and MEK inhibitor over another. Please refer to UM ONC_1279 Cotellic (cobimetinib) or UM ONC_1207 Zelboraf (vemurafenib) policy.	Step Therapy Criteria
UM ONC_1399	Photofrin (porfimer)	Positive change	Add inclusion criteria: C.Non-Small Cell Lung Cancer and Esophageal Cancer 1.Photofrin (porfimer) may be used as photodynamic palliation therapy in members with obstruction due to endobronchial non-small cell lung cancer (NSCLC) or esophageal cancer AND the members are not candidates for surgery and/or radiation.	Per FDA labeling
UM ONC_1401	Tukysa (tucatinib)	Positive change	Add inclusion criteria: B.Breast Carcinoma 1.Tukysa (tucatinib) may be used in members with metastatic HER-2 positive breast cancer who have experienced disease progression on ~~two~~ one or more anti HER-2 regimens in the metastatic setting~~, including a regimen containing [pertuzumab and trastuzumab] AND/OR either Kadcyla (ado-trastuzumab emtansine) or Enhertu (fam-trastuzumab deruxtecan).~~ C.Colorectal Cancer 1.Tukysa (tucatinib) may be used in combination with trastuzumab/trastuzumab biosimilars in members with HER-2 positive and RAS wild-type positive metastatic or unresectable colorectal cancer that has progressed following treatment with fluoropyrimidine, and oxaliplatin and/or irinotecan-based chemotherapy.	New FDA Indication

UM ONC_1401	Tukysa (tucatinib)	Negative change	Add exclusion criteria: A.Disease progression on Tukysa (tucatinib) or on another HER2 inhibitor ~~oral tyrosine kinase inhibitor~~ [e.g., Tykerb (lapatinib), Enhertu (fam-trastuzumab deruxtecan), Perjeta (pertuzumab), trastuzumab/trastuzumab biosimilar], unless time of anti-HER2 Tykerb (lapatinib) targeting therapy was received ≥ 12 months ago (for breast cancer indication only). B.Lack of documentation for the presence of HER2 protein overexpression and RAS wild-type in tumor specimens.	Per FDA labeling
UM ONC_1407	Trodelvy (sactizumab govitecan-hziy)	No Clinical Changes	N/A	N/A
UM ONC_1422	Tepmetko (tepotinib)	Positive change	Remove inclusion criteria: B.Non-Small Cell Lung Cancer 1.Tepmetko (tepotinib) may be used as monotherapy for members with metastatic/locally advanced Non-Small Cell Lung Cancer, with positive MET exon 14 skipping mutation confirmed by either tissue biopsy or liquid biopsy (e.g., Guardant 360 or an equivalent FDA approved test), and as initial or subsequent line therapy if was not used previously. ~~1.NOTE 1: Per NCH Policy, Tepmetko (tepotinib) is a non-preferred drug for members with recurrent/metastatic Non-Small Cell Lung Cancer with a positive MET exon 14 skipping mutation (MET positive NSCLC). The NCH preferred alternative in the above clinical situation is Trabecta (capmatinib). This position is based on the following:~~ ~~a.Lack of Level 1 evidence (randomized clinical trials and or meta-analyses) to show superior outcomes with Tepmetko (tepotinib) over Trabecta (capmatinib).~~ ~~b.Trabecta (capmatinib) has a full/regular FDA approval whereas Tepmetko just has an accelerated FDA approval(confirmatory trial data are awaited).~~ ~~2.NOTE 2: Tepmetko (tepotinib) may be used for members with recurrent/metastatic MET positive NSCLC if there is intolerance/contraindication to the NCH preferred alternative Trabecta (capmatinib).~~	Per FDA labeling
UM ONC_1424	Cosela (trilaciclib)	No Clinical Changes		N/A
UM ONC_1425	Fotivda (tivozanib)	Positive change	Remove inclusion criteria: B.Renal Cell Carcinoma (RCC) 1.Fotivda (tivozanib) may be used as a single agent for members with metastatic/unresectable renal cell carcinoma who have experienced disease progression on, a VEGFR Tyrosine Kinase inhibitor Tyrosine Kinase Inhibitor (e.g., lenvatinib, axitinib, cabozantinib or, pazopanib), ~~or bevacizumab~~) AND one or more Immune Checkpoint Inhibitor (e.g., pembrolizumab, nivolumab, avelumab, ipilimumab).	Per Clinical Trial Analysis/Criteria
UM ONC_1433	Jemperli (dostarlimab-gxly)	Positive change	Add inclusion criteria: D. Rectal Cancer 1. Jemperli (dostarlimab-gxly) may be used as monotherapy, for a period of 6 months, for members with locally advanced, treatment-naïve, mismatch repair deficiency(dMMR)/microsatellite instability-high(MSI-H) rectal cancer.	New FDA Indication

UM ONC_1433	Jemperli (dostarlimab-gxly)	Negative change	Add exclusion criteria: C.Treatment exceeds the maximum 6 months duration limit for Jemperli (dostarlimab-gxly) use in rectal cancer.	Per FDA labeling
UM ONC_1455	Scemblix (asciminib)	Negative change	Add exclusion criteria: C.Scemblix (asciminib) is being used on Philadelphia or BCR-ABL negative CML or in members with the following mutations: A337T, P465S.	Per Compendia Listing
UM ONC_1458	Enjaymo (sutimlimab-jome)	Positive change	Remove inclusion criteria: B.Cold Agglutinin Disease (CAD) 1.Enjaymo (sutimlimab-jome) may be used as monotherapy in members with a confirmed diagnosis of primary Cold Agglutinin Disease (CAD), a Hgb ≤ 10 g/dL within the last 4 weeks, and recent history of blood transfusion within 6 months . ~~2.If not already received, the member was vaccinated against meningococcus, hemophilus influenzae, and streptococcus pneumoniae.~~	Per Clinical Trial Analysis/Criteria