Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
New	Enjaymo (sutimlimab-jome)	N/A	N/A	N/A
New	Kimmtrak (tebentafusp-tebn)	N/A	N/A	N/A
UM ONC_1028	Avastin (bevacizumab)/Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr)	Negative change	Add inclusion criteria: B.Breast Cancer NOTE: Per NCH Pathway & NCH Policy, [Avastin (bevacizumab) + Taxol (paclitaxel)] is not recommended and is a non-preferred regimen for the treatment of advanced/metastatic breast cancer. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with [Avastin (bevacizumab) + Taxol (paclitaxel)] compared to NCH preferred regimens. Furthermore, the FDA removed the breast cancer indication for Avastin (bevacizumab) due to the lack of overall survival data and the risk outweighed the benefit for use in breast cancer. Please refer to NCH pathway for the preferred treatments in advanced/metastatic breast cancer. D. Non-Small Cell Lung Cancer (NSCLC) 1.NOTE: Avastin (bevacizumab)/Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr) containing regimens are non-preferred per NCH Policy & NCH Pathway for metastatic non-squamous Non-Small Cell Lung Cancer. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superiority of Avastin (bevacizumab) containing regimes compared to NCH preferred regimens. Please refer to the NCH Pathway document for the current recommended regimens in the above cancer type/stage.	NCH Pathway Exclusion
UM ONC_1130	Alimta or Pemfexy (Pemetrexed)	Negative change	Add inclusion criteria: B.Non-Small Cell Lung Cancer (NSCLC) 1.NOTE: Per NCH Pathway & NCH Policy, [Bevacizumab + Carboplatin/Cisplatin + Pemetrexed] followed by maintenance [Bevacizumab + Pemetrexed] is a non-preferred regimen. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes compared to NCH Preferred regimens for the initial treatment of NSCLC. Please refer to NCH Pathway for the preferred treatments recommended for use in the above setting. C.Malignant Pleural Mesothelioma b.As first line therapy for unresectable or metastatic disease as a single agent or in combination with cisplatin or carboplatin with or without bevacizumab OR c.As subsequent therapy as a single agent (if not previously used in the first line setting).	NCH Pathway Exclusion
UM ONC_1130	Alimta or Pemfexy (Pemetrexed)	Positive change	Remove inclusion criteria: B.Non-Small Cell Lung Cancer (NSCLC) d. ~~Continuation m~~Maintenance therapy as a single agent after response or stable disease following first-line therapy or maintenance therapy in combination with pembrolizumab following first-line therapy with [pembrolizumab + pemetrexed + cisplatin/carboplatin].	Per Compendia Listing
UM ONC_1132	Rituxan Products (Rituxan, Rituxan Hycela, Truxima, Ruxience)	Negative change	Add inclusion criteria: 1.The member is an adult or pediatric member ≥6 months of age who has CD20 positive B-cell NHL (eg., follicular, diffuse large B-cell, Mantle Cell Lymphoma, pediatric aggressive mature B-Cell Lymphomas) or B-AL and rituximab (Truxima or Ruxience) is being used as a single agent or in combination with chemotherapy for ANY of the following: a.Initial therapy (for use in combination with chemotherapy only)	Per Compendia Listing
UM ONC_1132	Rituxan Products (Rituxan, Rituxan Hycela, Truxima, Ruxience)	Negative change	Add exclusion criteria: A.Use of Rituximab products (Rituxan, Rituxan Hycela, Truxima, Ruxience, Riabni) as maintenance therapy after primary treatment of Diffuse Large B-Cell Lymphoma (DLBCL) or in combination with Imbruvica (ibrutinib). This recommendation is based on the lack of improvement in overall survival and the risk of toxicities outweigh the benefit. B.Treatment exceeds the maximum months duration limit of 2 years when used in combination with Venclexta (venetoclax) for the treatment of CLL.	Per Clinical Trial Analysis/Criteria
UM ONC_1132	Rituxan Products (Rituxan, Rituxan Hycela, Truxima, Ruxience)	Negative change	Add inclusion criteria: B.CD-20 positive B-Cell Non-Hodgkin's Lymphomas (NHL) or Acute Leukemia (B-AL) NOTE: Per NCH Pathway and NCH Policy, the following regimens are non-preferred due to lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes/lower toxicity compared to the NCH Preferred regimens. Please refer to NCH L1 pathway for the preferred treatments in these settings: a.In relapsed/refractory DLBCL: Gemcitabine + vinorelbine +/- rituximab; lenalidomide +/- rituximab (non-GCB DLBCL) b.As primary therapy for Follicular Lyphoma: lenalidomide + rituximab c.As initial and subsequent therapy for Marginal Zone Lymphoma: lenalidomide + rituximab d.As second line or subsequent therapy for Mantle Cell Lymphoma: Ibrutinib + lenalidomide + rituximab; venetoclax + rituximab. C.Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) NOTE: Per NCH Pathway & NCH Policy, the following regimens are non-preferred based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes compared to NCH preferred regimens. Please refer to NCH pathway for the preferred treatments in the treatment of CLL/SLL. a.First Line therapy: single agent rituximab; rituximab + ibrutinib; rituximab + fludarabine; rituximab + high-dose methylprednisolone (HDMP) b.Second line or subsequent therapy: as a single agent in dose-dense regimen; rituximab + high-dose methylprednisolone (HDMP); rituximab + alemtuzumab.	NCH Pathway Exclusion

Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
UM ONC_1193	Revlimid (lenalidomide)	Positive change	Add inclusion criteria: B.Multiple Myeloma (MM) 1.The member has multiple myeloma and Revlimid (lenalidomide) may be used as ONE of the following: a.Initial therapy: i.ii.In combination with Cyotxan (cyclopohosphamide) +/- dexamethasone c.For relapsed or refractory disease as ONE of the following: vii.With Treanda/Bendeka/Belrapzo (bendamustine) +/- dexamethasone viii.With Cytoxan (cyclopohosphamide) +/- dexamethasone	Per Compendia Listing
UM ONC_1193	Revlimid (lenalidomide)	Negative change	Remove inclusion criteria: B.Multiple Myeloma (MM) vii.With Farydak (panobinostat) in members who have progressed on 2 prior regimens.	NCCN Withdrawal
UM ONC_1193	Revlimid (lenalidomide)	Negative change	Add inclusion criteria: B.Multiple Myeloma (MM) 1.Note: Per NCH pathway & NCH policy, the following regimens are non-preferred in the treatment of multiple myeloma: a.Initial therapy: Daratumumab + lenalidomide + bortezomib +/- dexamethasone; Ixazomib + lenalidomide +/- dexamethasone; Daratumumab + carfilzomib + lenalidomide +/- dexamethasone a.Subsequent therapy: Panobinostat + lenalidomide +/- dexamethasone. The above recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes compared to NCH preferred regimens. When clinically appropriate, please refer to NCH pathway for the preferred treatments. D.Non-Hodgkin Lymphoma (NHL) 1.Note: Per NCH Pathway & NCH Policy, the following regimens are non-preferred for the following treatment settings: a.Diffuse Large B Cell Lymphoma (DLBCL) maintenance: single agent Revlimid (lenalidomide) a.Diffuse Large B Cell Lymphoma (DLBCL), relapsed/refractory: Lenalidomide +/- rituximab (non-GCB DLBCL) a.Follicular Lymphoma (FL), initial therapy: Lenalidomide + rituximab/obinutuzumab a.Marginal Zone Lymphomas (MZL), initial therapy: Lenalidomide + rituximab a.Mantle Cell Lymphoma (MCL), second line and subsequent therapy: ibrutinib + lenalidomide + rituximab. The above recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes compared to NCH preferred regimens. When clinically appropriate, please refer to NCH pathway for the preferred treatments.	NCH Pathway Exclusion
UM ONC_1194	Nexavar (sorafenib)	Positive change	Remove inclusion criteria: B.Renal Cell Carcinoma (RCC) NOTE: The preferred tyrosine kinase inhibitor, per NCH Policy & NCH Pathway in the subsequent line of therapy for advanced or metastatic RCC, is Cabometyx (cabozantinib) over Nexavar (sorafenib). Please refer to UM ONC_1237 Cometriq or Cabometyx (cabozantinib) policy.	NCH Pathway Expansion
UM ONC_1194	Nexavar (sorafenib)	Negative change	Add inclusion criteria: B.Renal Cell Carcinoma (RCC) 1.NOTE: Per NCH Pathway & NCH Policy, Nexavar (sorafenib) is a non-preferred regimen based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with Nexavar (sorafenib) compared to NCH Preferred regimens. Please refer to NCH Pathway for the preferred treatments recommended for use in RCC.	NCH Pathway Exclusion
UM ONC_1194	Nexavar (sorafenib)	Negative change	Add inclusion criteria: C.Hepatocellular Carcinoma (HCC) 1.NOTE: Per NCH Pathway & NCH Policy, Nexavar (sorafenib) is a non-preferred regimen based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with Nexavar (sorafenib) compared to NCH Preferred regimens. Please refer to NCH Pathway for the preferred treatments recommended for use in HCC.	NCH Pathway Exclusion
UM ONC_1194	Nexavar (sorafenib)	Positive change	Remove inclusion criteria: C.Hepatocellular Carcinoma (HCC) 1.The preferred agents, per NCH Policy & NCH Pathway, for unresectable or metastatic HCC are as follows: a.For first line treatment: Tecentriq (atezolizumab) + Avastin (bevacizumab) b.For subsequent treatment: Stivarga (regorafenib).	NCH Pathway Expansion
UM ONC_1194	Nexavar (sorafenib)	Negative change	Add inclusion criteria: 2.Nexavar (sorafenib) use is supported as a single agent in members with Child-Pugh Class A or B unresectable HCC, in the subsequent line setting, if the member has intolerance/contraindication to/disease progression on Stivarga (regorafenib) AND Lenvima (lenvatinib).	More Cost Effective Alternative(s)
UM ONC_1197	Sutent (sunitnib)	Positive change	Remove inclusion criteria: B.Renal cell carcinoma (RCC) 1.NOTE: The preferred tyrosine kinase inhibitor, per NCH policy and NCH pathway for advanced or metastatic RCC, IMDC Good Risk disease is Votrient (pazopanib). The latter recommendation is based upon the data from the COMPARZ trial. Please see UM ONC_1195 Votrient (pazopanib) policy.	NCH Pathway Expansion

Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
UM ONC_1197	Sutent (sunitnib)	Negative change	Add inclusion criteria: B.Renal cell carcinoma (RCC) 1.NOTE: Per NCH Pathway & NCH Policy, Sutent (sunitinib) is a non-preferred regimen based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with Sutent (sunitinib) compared to Votrient (pazopanib). This recommendation is based on the data from the COMPARZ and PISCES trials demonstrating Votrient (pazopanib) is equally effective as Sutent (sunitinib) and is better tolerated. 1.2.Sutent (sunitnib) may be used in members with metastatic/recurrent/unresectable metastatic Renal Cell Carcinoma with IMDC Good Risk disease, in members who are intolerant to, or have a contraindication to, or disease progression on the use of Votrient (pazopanib). Add inclusion criteria: D.Pancreatic Neuroendocrine tumor (PNET) 1.Sutent (sunitinib) may be used as a single agent for members with unresectable or metastatic pancreatic neuroendocrine tumor, in any line of therapy , if not previously used.	NCH Pathway Exclusion
UM ONC_1197	Sutent (sunitnib)	Negative change	Add exclusion criteria: C.Treatment with Sutent (sunitinib) exceeds the maximum duration limit of 120 (12.5mg), 60 (25mg), 30 (37.5 mg) and 30 (50 mg) capsules a month.	FDA labeling
UM ONC_1204	Caprelsa (vandetanib)	Negative change	Remove inclusion criteria: B.Thyroid Cancer 1.Caprelsa (vandetanib) may be used as monotherapy for members with any of the following: a.Unresectable or metastatic medullary thyroid cancer OR b.Unresectable or metastatic papillary, follicular, or Hürthle cell thyroid cancer deemed refractory to/unlikely to benefit from radioactive iodine treatment.	Per Compendia Listing
UM ONC_1206	Xalkori (crizotinib)	Positive change	Add inclusion criteria: B.Non-Small Cell Lung Cancer (NSCLC) 1.NOTE: The preferred agents, per NCH Pathway & NCH Policyies, for first line therapy of metastatic , ALK+ NSCLC areis Alecensa (alectinib) and Alunbrig (brigatinib) . This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with other ALK inhibitors [specifically e.g., Zykadia (ceritinib), Lorbrena (lorlatinib), Xalkori (crizotinib)] over Alecensa (alectinib) and Alunbrig (brigatinib). Please refer to UMC ONC_1277 Alecensa (alectinib) policy or UM ONC_1313 Alunbrig (brigatinib) policy.	NCH Pathway Expansion
UM ONC_1206	Xalkori (crizotinib)	Positive change	Add inclusion criteria: B.Non-Small Cell Lung Cancer (NSCLC) 3.The member has locally advanced, recurrent, or metastatic NSCLC and Xalkori (crizotinib) may be used as a single agent for any of the following: a.ROS1 rearrangement-positive tumors without brain metastases as first line or subsequent therapy OR b.ALK-positive tumors for members who are intolerant to/have a contraindication to/have failed therapy with Alecensa (alectinib) or Alunbrig (brigatinib).	NCH Pathway Expansion
UM ONC_1206	Xalkori (crizotinib)	Negative change	Add inclusion criteria: D.ALK+ Anaplastic Lymphoma (ALCL) 1.Xalkori (crizotinib) may be used as a single agent for members 21 years old or younger with relapsed/refractory Anaplastic Large Cell Lymphoma that is: a.Positive for ALK:- Anaplastic Lymphoma Kinase (confirmed by testing), AND b.The member has experienced disease progression on at least one prior therapy.	Per Compendia Listing
UM ONC_1206	Xalkori (crizotinib)	Negative change	Add inclusion criteria: D.ALK+ Anaplastic Lymphoma (ALCL) 1.Xalkori (crizotinib) may be used as a single agent for members 21 years old or younger with relapsed/refractory Anaplastic Large Cell Lymphoma that is: a.Positive for ALK:- Anaplastic Lymphoma Kinase (confirmed by testing), AND b.The member has experienced disease progression on at least one prior therapy.	Per Compendia Listing
UM ONC_1215	Treanda/Bendeka/Belrapzo (bendamustine)	Negative change	Add exclusion criteria: B.Dosing exceeds single dose limit of Xalkori (crizotinib) 250 mg (for NSCLC); 500 mg (for ALCL). C.Treatment exceeds the maximum limit of 12060 (250mg) or 60 (200 mg) capsules a month.	FDA labeling
UM ONC_1224	Kyprolis (carfilzomib)	Positive change	Remove inclusion criteria: B.Multiple Myeloma (MM) 2.NOTE 2: For initial therapy of newly diagnosed multiple myeloma, both transplant eligible and transplant ineligible, Kyprolis (carfilzomib) based regimens are non-preferred per NCH Pathway & NCH Policy: Please refer to the NCH Pathway document for preferred/Level 1 recommended therapies for the initial treatment of Multiple Myeloma.	NCH Pathway Expansion

Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
UM ONC_1224	Kyprolis (carfilzomib)	Negative change	Add inclusion criteria: B.Multiple Myeloma (MM) 2.NOTE 2: [Carfilzomib + Daratumumab + Lenalidomide +/- Dexamethasone] and [Carfilzomib + Panobinostat] are Non-Preferred regimens for the treatment of MM. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes/lower toxicity compared to the NCH Preferred regimens. When clinically appropriate, please refer to NCH pathway for the preferred treatments. 3.For relapsed or refrac tory disease, Kyprolis (carfilzomib) may be used in ANY of the following: a.In combination with or without dexamethasone OR b.In combination ~~with dexamethasone and~~ lenalidomide +/- dexamethasone OR c.In combination ~~with dexamethasone and~~ cyclophosphamide +/- dexamethasone OR d.In combination with daratumumab +/- dexamethasone ~~if the member has not received prior therapy with daratumumab~~OR e.In combination ~~with dexamethasone and~~ pomalidomide +/- dexamethasone if the member has failed 2 prior regimens or line of therapies that include one proteasome inhibitor (e.g., bortezomib, ixazomib, carfilzomib) & one immunomodulatory agent (e.g., lenalidomide, thalidomide).	NCH Pathway Exclusion
UM ONC_1226	Zaltrap (ziv-aflibercept)	Negative change	Add inclusion criteria: Colorectal Cancer 1.NOTE: Per NCH Policy & NCH Pathway, Zaltrap (ziv-aflibercept) is a NON-PREFERRED drug for metastatic colorectal cancer. Zaltrap (ziv-aflibercept) use is not recommended for metastatic colorectal cancer. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with Zaltrap (ziv-aflibercept) based regimens compared to Avastin (bevacizumab/Avastin biosimilars) based regimens or NCH Preferred regimens. When clinically appropriate, please refer to NCH pathway for the preferred treatments for metastatic colorectal cancer.	NCH Pathway Exclusion
UM ONC_1226	Zaltrap (ziv-aflibercept)	Positive change	Remove exclusion criteria: A.NOTE: Per NCH Policy & NCH Pathway Zaltrap (ziv-aflibercept) is a NON-PREFERRED drug for metastatic colorectal cancer. Zaltrap is not recommended for use in metastatic colorectal cancer based on a lack of level one evidence from randomized trial/meta-analysis demonstrating superior outcomes over Avastin (bevacizumab) containing regimens.	NCH Pathway Exclusion
UM ONC_1232	Stivarga (regorafenib)	No Clinical Changes	N/A	N/A
UM ONC_1261	Cyramza (ramucirumab)	Negative change	Add inclusion criteria: B.Gastric and Gastroesophageal Junction Cancers 1.NOTE: Cyramza (ramucirumab) is a non-preferred agent per NCH Policy & NCH Pathway. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with Cyramza (ramucirumab) compared to NCH Preferred regimens.~~The preferred alternatives per NCH Policies & NCH Pathway, for subsequent therapy of advanced/metastatic gastric or gastroespophageal junction adenocarcinoma are single agents including paclitaxel, docetaxel, or irinotecan.~~ C.Non-Small Cell Lung Cancer (NSCLC)/Colorectal Carcinoma/Hepatocellular Carcinoma 1.Cyramza (ramucirumab) is a non-preferred drug for the treatment of all the above cancer types. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with Cyramza (ramucirumab) compared to NCH Preferred regimens. Please refer to the NCH Pathway document for recommended/preferred regimens/agents for the above cancer types.	NCH Pathway Exclusion
UM ONC_1262	Imbruvica (ibrutinib)	Negative change	Add inclusion criteria: B.Mantle Cell Lymphoma (MCL) NOTE: Per NCH Pathway & NCH Policy, [Ibrutinib + Lenalidomide + Rituximab] and [Ibrutinib + Venetoclax] are both Non-Preferred regimens for the treatment of MCL. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with the above regimens compared to NCH Preferred regimens. When clinically appropriate, please refer to NCH Pathway for the preferred treatments.	NCH Pathway Exclusion
UM ONC_1262	Imbruvica (ibrutinib)	Positive change	Add inclusion criteria: C.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 Venetoclax is supported 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).	NCH Pathway Expansion
UM ONC_1263	Keytruda (pembrolizumab)	Positive change	Remove inclusion criteria: C.Recurrent/Metastatic Squamous and Non-Squamous Non-Small Cell Lung Cancer (NSCLC) 1.NOTE: The preferred agent, per NCH Policy and NCH Pathway, for first line and maintenance treatment of recurrent/metastatic NSCLC is Keytruda (pembrolizumab) over other PD-1 or PD-L1 inhibitors [i.e., Opdivo (nivolumab), Tecentriq (atezolizumab)].	NCH Pathway Expansion

Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
UM ONC_1263	Keytruda (pembrolizumab)	Negative change	Add inclusion criteria: C.Recurrent/Metastatic Squamous and Non-Squamous Non-Small Cell Lung Cancer (NSCLC) 1.NOTE: Per NCH Pathway & NCH Policy, [Pembrolizumab + Carboplatin + Albumin-bound Paclitaxe] is a non-preferred regimen for the treatment of NSCLC, based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes compared to NCH Preferred regimens. Please refer to NCH Pathway for the preferred treatments. 1.2.NOTE: Keytruda (pembrolizumab) use as first line therapy for non-squamous/adenocarcinoma Non-Small Cell Lung Cancer, as a single agent or in combination with platinum-based chemotherapy REQUIRES that the member's NSCLC be negative for EGFR mutations and ALK rearrangements. F.Urothelial Carcinoma including Upper Urinary Tract Carcinoma and Carcinoma of Urethra 3.2.Keytruda may be used as monontherapy	NCH Pathway Exclusion
UM ONC_1263	Keytruda (pembrolizumab)	Negative change	F.Urothelial Carcinoma including Upper Urinary Tract Carcinoma and Carcinoma of Urethra 2.Keytruda may be used as monontherapy H.Gastric Cancer or Esophageal and Esophagogastric Junction Cancers a.As first line therapy in combination with fluoropyrimidine and platinum containing chemotherapy +/- trastuzumab (if HER positive) , AND CPS of 10 or higher . This position is supported by the lack of survival benefit of pembrolizumab monotherapy/pembrolizumab +chemotherapy for tumors expressing lower levels of PD-L1. J.Hepatobiliary Cancers 1.NOTE: Keytruda use in this disease is limited to members with liver function of Child Pugh Class A only, and members who have not received previous therapy with an immune checkpoint inhibitor (e.g., Tecentriq). O.Cutaneous Squamous Cell Carcinoma (CSCC) 1.NOTE: The preferred agent, per NCH Policy, for the treatment of members with recurrent or metastatic cutaneous squamous cell carcinoma is Libtayo (cemiplimab-rwlc) over Keytruda (pembrolizumab). This position is based on the lack of Level 1 Evidence (randomized trials and or meta-analyses) to show superior outcomes with Keytruda compared to Libtayo. Please refer to UM ONC_1089 for Libtayo (cemiplimab-rwlc) policy. O.Cutaneous Squamous Cell Carcinoma (CSCC) 1.NOTE: The preferred agent, per NCH Policy, for the treatment of members with recurrent or metastatic cutaneous squamous cell carcinoma is Libtayo (cemiplimab-rwlc) over Keytruda (pembrolizumab). This position is based on the lack of Level 1 Evidence (randomized trials and or meta-analyses) to show superior outcomes with Keytruda compared to Libtayo. Please refer to UM ONC_1089 for Libtayo (cemiplimab-rwlc) policy. P.Microsatellite Instability-High or Mismatch Repair Deficient Cancer 1.Keytruda (pembrolizumab) may be used in members with a metastatic /unresectable solid tumor that has progressed following prior treatment, including all satisfactory treatment alternatives and the solid tumor is positive for microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) as confirmed by any standardized test for the above biomarker. Q.Triple Negative Breast Cancer (TNBC) 1.Keytruda (pembrolizumab) may be used in combination with chemotherapy for any of the following: a.As neoadjuvant ~~or adjuvant therapy (if the member received pembrolizumab in the neoadjuvant setting)~~ in a members with newly diagnosed high-risk early-stage TNBC (a tumor size >1 cm, ≤2 cm in diameter with nodal involvement, or tumor size >2 cm in diameter regardless of nodal involvement) AND the members have not received prior checkpoint inhibitor (PD-1/PD-L1) therapy, regardless of tumor PD-L1 expression b.As adjuvant therapy (ONLY if the member received pembrolizumab in the neoadjuvant setting) AND a.c.The member has not received prior checkpoint inhibitor (PD-1/PD-L1) therapy	Per Clinical Trial Analysis/Criteria
UM ONC_1271	Farydak (panobinostat)	Negative change	Add inclusion criteria: 2.Note: Farydak (panobinostat) and Farydak containing regimens are Not Recommended for use per NCH Policy. This statement is based on the fact that several safer and more effective alternatives are available.	NCCN Withdrawal
UM ONC_1273	Lynparza (olaparib)	Positive change	Remove inclusion criteria: B.Ovarian Cancer NOTE: The Preferred PARP inhibitor, per NCH Policies and NCH Pathways, for maintenance therapy-either first line or after a platinum-sensitive relapse-in ovarian cancer is Zejula (niraparib) . This recommendation is based on a lack of level 1 evidence (randomized trials and/or meta-analyses) demonstrating superiority of Lynparza (olaparib) over Zejula (niraparib). Please refer to UM ONC_1307 Zejula (niraparib) policy. E.D.Prostate Cancer 1.NOTE: Lynparza (olaparib) is only recommended in metastatic castration-resistant prostate cancer with mutations in DNA repair genes including but not limited to germline/somatic BRCA1 or BRCA2 deleterious/suspected deleterious mutations.	NCH Pathway Expansion

Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
UM ONC_1273	Lynparza (olaparib)	Negative change	Add inclusion criteria: B.Ovarian Cancer 1.NOTE: Per NCH Policy and NCH Pathway, the combination of Lynparza (olaparib) and Avastin (bevacizumab) for maintenance therapy of advanced ovarian cancer, is a non-preferred regimen. The preferred regimen in the above setting in single agent Zejula (niraparib). NCH Policy does not support [Olaparib + Bevacizumab] for first line maintenance therapy, after completion of platinum based therapy. This recommendation is based on the lack of Level 1 evidence showing superior outcomes with the above combination compared to Lynparza (olaparib) monotherapy. 3.2.Lynparza (olaparib tablet) may be used as single agent for ANY of the following: a.First line maintenance therapy: For members with stage II- IV ovarian cancer, with a deleterious/suspected deleterious germline or somatic BRCA 1/2 mutation or homologous recombination deficiency (HRD), who have completed first line platinum-based chemotherapy, and Lynparza is being given as a single agent in the maintenance setting. b.For members with recurrent/metastatic ovarian cancer with or without a deleterious/suspected deleterious germline/somatic BRCA 1/2 mutation, who have completed platinum-based therapy for platinum-sensitive relapse. c.Members with recurrent/metastatic ovarian cancer, with a deleterious/suspected deleteriou s germline/somatic BRCA 1/2 mutation, who have disease progression after 3 or more lines of prior therapy.	NCH Pathway Exclusion
UM ONC_1273	Lynparza (olaparib)	Negative change	Add inclusion criteria: C.Breast Cancer 1.Member is positive for a deleterious/suspected deleterious germline BRCA 1/2 mutation and has metastatic/recurrent breast cancer, regardless of HER2 and ER/PR-status AND Lynparza (olaparib) will be used as monotherapy 2.Lynparza (olaparib) may be use as adjuvant therapy for early stage (stages I-III)/non-metastatic HER2 negative breast cancer if the member is that is positive for agermline BRCA 1 or BRCA 2 mutation. Pancreas Adenocarcinoma 1.Lynparza (Olaparib) may be usedwill be use as monotherapy in a Mmember has with a deleterious/suspected deleterious germline BRCA 1/2 mutation who and has metastatic pancreatic adenocarcinoma with stable ~~/responding~~ disease after 4-6 months of first line platinum-based chemotherapy (including cisplatin + gemcitabine or an oxaliplatin-based regimen).	Per Compendia Listing
UM ONC_1283	Lenvima (lenvatinib)	Negative change	Add inclusion criteria: B.Thyroid Cancer 2.The member has anaplastic thyroid carcinoma and Lenvatinib is being used as monotherapy as first or subsequent line therapy	Per Compendia Listing
UM ONC_1283	Lenvima (lenvatinib)	Positive change	Remove inclusion criteria: C.Renal Cell Carcinoma (RCC) 1.NOTE: The preferred tyrosine kinase inhibitor, per NCH Policies & NCH Pathway, for first line metastatic RCC is: a.Votrient (pazopanib) for good risk disease b.Cabometyx (cabozantinib) for intermediate or poor risk disease. D.Hepatocellular Carcinoma (HCC) 1.NOTE: The preferred regimen, per NCH Policies & NCH Pathway, for first line therapy of unresectable or metastatic HCC is [Tecentriq (atezolizumab) + Avastin (bevacizumab)]. 1.Lenvima (lenvatinib) may will be used as monotherapy for members with unresectable or metastatic hepatocellular cancer. ~~Lenvima (lenvatinib) is preferred for members with no worse than Child-Turcotte-Pugh class A cirrhosis.~~	NCH Pathway Expansion
UM ONC_1283	Lenvima (lenvatinib)	Negative change	Add inclusion criteria: 1.Lenvima (lenvatinib) may be used in metastatic renal cell carcinoma as a single agent ~~for any line of therapy for non-clear cell carcinoma~~ OR with Afinitor (everolimus) as subsequent therapy ~~for clear cell carcinoma~~ who have experienced disease progression on prior therapy with an anti-angiogenesis agent (an oral TKI and/or bevacizumab) AND an immune checkpoint inhibitor. 2.NOTE: Keytruda(pembrolizumab) + Lenvima(lenvatinib) is a Non-Preferred regimen per NCH Policy for any line of therapy for metastatic renal cell carcinoma. This position is based on the lack of Level 1 evidence (randomized trials and or meta-analyses) showing superior outcomes with the above regimen compared to the regimens recommended per NCH Policy and NCH Pathway.	Per Compendia Listing
UM ONC_1283	Lenvima (lenvatinib)	Negative change	Add exclusion criteria: A.Disease progression while taking Lenvima (lenvatinib) or on a prior lenvatinib containing regimen. B. ~~Member with grade 3 or 4 renal failure/impairment or hepatotoxicity.~~ C.The max dose should not exceed 24 mg/day for thyroid cancer, 18 20 mg/day for renal cell cancer, 12 mg/day for hepatocellular cancer, and 20 mg/day for endometrial cancer. D.Treatment exceeds the maximum monthly limit of ~~30 (24 mg); 30 (20 mg); 30 (18 mg); 30 (14 mg); 30 6~~0 (10 mg); 30 (8 mg), or 30 (4 mg).	FDA labeling

Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
UM ONC_1284	Ninlaro (ixazomib)	Negative change	Add inclusion criteria: B.Multiple Myeloma 1.NOTE: Ninlaro (ixazomib) c 1.Ninlaro (ixazomib) may be used for members who have experienced disease progression on, contraindications, or intolerance to NCH Preferred Velcade (bortezomib) based regimens, Revlimid (lenalidomide), AND Darzalex (daratumumab) in ANY of the following as follows: a.As initial or subsequent therapy : Ixazomib +/- Dexamethasone +/- Lenalidomide; Ixazomib + Cyclosphosphamide +/- Dexamethasone b.As single agent maintenance therapy. c.Ixazomib + Pomalidomide +/- Dexamethasone may be used as subsequent therapy following two prior lines of therapy including an immunomodulatory agent (e.g., lenalidomide, thalidomide) and a proteasome inhibitor (e.g., bortezomib, carfilzomib). a.~~In combination with Decadron (dexamethasone) with or without Revlimid (lenalidomide)~~ ~~b.In combination with Cytoxan (cyclophosphamide) and Decadron (dexamethasone)~~ ~~c.In combination with Decadron (dexamethasone) and Pomalyst (pomalidomide).~~	NCH Pathway Exclusion
UM ONC_1284	Ninlaro (ixazomib)	Negative change	Add exclusion criteria: A.Disease progression on Ninlaro (ixazomib) or Ninlaro (ixazomib) containing regimen.	Per Compendia Listing
UM ONC_1297	Venclexta (venetoclax)	Positive change	Remove inclusion criteria: B.Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) 1.NOTE: Please note that per NCH Policy & NCH Pathway, the combination of Venclexta (venetoclax) and Gazyva (obinutuzumab) for first line therapy of CLL/SLL is a Non-Preferred Regimen. This recommendation is based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) to show superior outcomes with the above combination when compared with Venclexta (venetoclax) and Rituximab biosimilars.	NCH Pathway Expansion
UM ONC_1297	Venclexta (venetoclax)	Negative change	Add inclusion criteria: C.Acute Myeloid Leukemia (AML) 1.Venclexta (venetoclax) may be used in combination with either Dacogen (decitabine), or Vidaza (azacitidine), or low dose cytarabine for members with AML who have unfavorable-risk cytogenetics or are unsuitable for intensive remission induction therapy or decline intensive therapy; either of the above combinations may be used for remission induction therapy & post-remission therapy OR 1.2.Venclexta (venetoclax) may be used in combination with Dacogen (decitabine), Vidaza (azacitidine), or low dose cytarabine for members with relapsed/refractory AML.	Per Compendia Listing
UM ONC_1297	Venclexta (venetoclax)	Negative change	Add inclusion criteria: D.Mantle Cell Lymphoma Note: Per NCH Policy & NCH Pathway, [Venclexta (venetoclax) +/- rituximab] and [Venclexta (venetoclax) + Imbruvica (ibrutinib)] are non-preferred regimens based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes compared to NCH preferred regimens. Please refer to NCH pathway for the preferred treatments for relapsed/refractory 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, if the member is intolerant to/has a contraindication to/has experienced disease progression on any of the NCH Pathway recommended therapies.	NCH Pathway Exclusion
UM ONC_1297	Venclexta (venetoclax)	Negative change	Remove exclusion criteria: B.Exclusions described above for specific diagnoses.	NCH Pathway Expansion
UM ONC_1297	Venclexta (venetoclax)	Negative change	Add exclusion criteria: C.Treatment exceeds the maximum limit of ~~180~~120 (100 mg) or ~~240~~120 (50 mg), 5 (10mg) tablets per month. D.Treatment exceeds the maximum months duration limit of 12 months when used in combination with Gazyva (Obinutuzumab) or with Imbruvica (ibrutinib) for the treatment of CLL (unless the the member is MRD+ at the end of 12 months). Venclexta (venetoclax) + rituximab may be used up to 2 years duration limit.	FDA labeling
UM ONC_1301	Rubraca (rucaparib)	Positive change	Remove inclusion criteria: B.Ovarian Cancer 1.NOTE: Rucaparib is a non-preferred PARP-inhibitor per NCH Policy for ovarian cancer. The preferred PARP inhibitor is Zejula (niraparib). Please refer to UM ONC_1307 Zejula (niraparib) policy. C.Prostate Cancer 1.NOTE: Per NCH Pathway & NCH Policy, Rubraca is a non-preferred regimen for the treatment of metastatic castration-resistant prostate cancer.The preferred agent in this setting is Lynparza (Olaparib). This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with Rubraca (rucaparib) compared to Lynparza (olaparib). Please refer to UM ONC_1273 Lynparza (olaparib) policy.	NCH Pathway Expansion

Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
UM ONC_1301	Rubraca (rucaparib)	Negative change	Remove inclusion criteria: B.Ovarian Cancer 2.1.Rucaparib may be used as a single agent when ALL of the following criteria are met: a.The member has stage II - ~~III/~~IV ovarian carcinoma AND b.Member has relapsed or has progressive disease with a deleterious/suspected deleterious germline/ somatic BRCA1/2 mutation AND ~~i.Member has received at least 3 prior chemotherapy regimens OR~~ ii.i.Member has completed two or more lines of platinum-based therapy with a complete or partial response AND c.Rubraca (rucaparib) will be used as a single agent ~~and as maintenance therapy.~~ C.Prostate Cancer 2.1.Rucaparib may be used as a single agent in prostate cancer when ALL the following criteria are met: a.Member has metastatic Castration-Resistant Pprostate Cancer AND b.Member has experienced disease progression on an or after ~~taxane based therapy (e.g., docetaxel)~~ and Androgen Receptor Directed therapy (e.g., Abiraterone and/or Enzalutamide) AND c.Member's cancer is positive for BRCA 1 or 2 mutation (on germline testing- on the patient and/or somatic testing on the tumor tissue) ~~AND~~ ~~d.Member is intolerant to/has a contraindication to Lynparza (olaparibolaparib).~~	NCH Pathway Expansion
UM ONC_1301	Rubraca (rucaparib)	Negative change	Add exclusion criteria: A.Disease progression while receiving Rubraca (rucaparib) or another PARP inhibitor [(i.e.,Zejula (niraparib) or Lynparza (Olaparib). C.Concurrent use with ~~other PARP inhibitors~~ chemotherapy.	FDA labeling
UM ONC_1304	Generic Drugs	Positive change	Remove inclusion criteria: Add Siklos	FDA labeling
UM ONC_1307	Zejula (niraparib)	Positive change	Remove inclusion criteria: B.Ovarian Cancer 1.Niraparib monotherapy may be used in ANY one of the following: a.The member has newly diagnosed stage II-IV ovari an carcinoma and has undergone surgery (with or without optimal debulking) and has completed first line platinum-based chemotherapy AND Niraparib is being used as a single agent for maintenance therapy (regardless of BRCA mutation test results). b. ~~NOTE: Niraparib is the Preferred agent per NCH Policy & NCH Pathway in this setting. This recommendation is based on the lack of Level 1 evidence (randomized clinical trial and or meta-analyses) to support the superiority of other maintenance regimens, specifically Lynparza (Olaparib) and [Lynparza (olaparib) + Avastin (bevacizumab)] over Zejula (niraparib) alone.~~ c. The member has recurrent platinum-sensitive ovarian cancer and Niraparib is being used as a single agent for maintenance therapy, after completion of platinum-based chemotherapy (regardless of BRCA mutation test results).. ~~NOTE: Zejula (niraparib) is the Preferred agent per NCH Policy & NCH Pathway in this setting.~~ d.The member has a deleterious/suspected deleterious germline/somatic BRCA 1 /2 mutation has with recurrent ovarian cancer (regardless of platinum sensitivity) and has had 3 or more prior lines of chemotherapy and Niraparib is being used as a single agent.	NCH Pathway Expansion
UM ONC_1311	Lonsurf (trifluridine/tipiracil)	Positive change	Remove inclusion criteria: B.Colorectal Cancer 1.NOTE: Lonsurf + Avastin/biosimilars is a Non-Preferred regimen per NCH Policy. 1.The member has unresectable/advanced/metastatic colorectal cancer and Lonsurf	NCH Pathway Expansion
UM ONC_1311	Lonsurf (trifluridine/tipiracil)	Positive change	Add inclusion criteria: B.Colorectal Cancer 1.The member has unresectable/advanced/metastatic colorectal cancer and Lonsurf (trifluridine/tipiracil) is being used as a single agent or in combination with bevacizumab in members who have progressed through all clinically appropriate regimens for the above disease ~~except Stivarga (regorafenib) and Lonsurf (trifluridine/tipiracil).~~	Per Compendia Listing
UM ONC_1311	Lonsurf (trifluridine/tipiracil)	Negative change	Add inclusion criteria: C.Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma 1.The member is not a surgical candidate or has unresectable/locally advanced/recurrent/ metastatic Gastric or GEJ (Gastro-Esophageal Junction) adenocarcinoma and Lonsurf (trifluridine/tipiracil) is being used as third-line or subsequent therapy following 2 prior lines of therapy as a single agent.	Per Compendia Listing
UM ONC_1311	Lonsurf (trifluridine/tipiracil)	Negative change	Add exclusion criteria: B.Dosing exceeds single dose limit of Lonsurf (trifluridine/tipiracil) 80 mg (based on the trifluridine component).. C.Treatment exceeds the maximum limit of 80 (20 mg) or 120 ~~60~~ (15 mg) tablets/month.	FDA labeling
UM ONC_1314	Imfinzi (durvalumab)	Positive change	Remove inclusion criteria: C.Small Cell Lung Cancer (Extensive Stage) 1.NOTE: Per NCH Policy and NCH Pathway, the preferred checkpoint inhibitor for first line therapy of Extensive Stage Small Cell Lung Cancer is Tecentriq (atezolizumab). Please refer to the NCH Pathway document. This recommendation is based on the lack of Level 1 evidence (randomized trial and/or meta-analysis) to support superior outcomes with Imfinzi (durvalumab) based therapy over Tecentriq (atezolizumab) based therapy, in first line treatment of extensive-stage small cell lung cancer.	NCH Pathway Expansion

Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
UM ONC_1314	Imfinzi (durvalumab)	Positive change	Add inclusion criteria: C.Small Cell Lung Cancer (Extensive Stage) 1.Imfinzi (durvalumab) may be used in combination with [carboplatin/ cisplatin + etoposide] followed by single agent maintenance Imfinzi (durvalumab), for members with extensive stage small cell lung cancer, ~~if there is a history of intolerance to Tecentriq (atezolizumab).~~	Per Compendia Listing
UM ONC_1314	Imfinzi (durvalumab)	Negative change	Add exclusion criteria: D.Dosing exceeds single dose limit of Imfinzi (durvalumab) 10mg/kg (every 2 weeks), 20 mg/kg (every 3 weeks), 1500 mg (every 3 weeks for SCLC), or 1500 mg (every 4 weeks), or maximum duration of 12 months for NSCLC consolidation therapy.	FDA labeling
UM ONC_1362	Polivy (polatuzumab vedotin)	Positive change	Add inclusion criteria: B.Diffuse Large B-Cell Lymphoma (DLBCL) 1.The member has relapsed/refractory DLBCL and Polivy (polatuzumab vedotin) is being used as a single agent or in combination with bendamustine and with or without rituximab	Per Compendia Listing
UM ONC_1365	Xpovio (selinexor)	Positive change	Remove inclusion criteria: B.Multiple Myeloma 1.NOTE: Xpovio (selinexor) is a Non-Preferred drug for use in Multiple Myeloma per the NCH Policy. Several other alternative treatment options are available. C.Diffuse Large B-cell Lymphoma (DLBCL) 1.NOTE: Xpovio (selinexor) is a Non-Preferred drug per NCH Policy, for relapsed/refractory Diffuse Large B-Cell Lymphoma (and all related Large B-Cell Lymphomas).	NCH Pathway Expansion
UM ONC_1365	Xpovio (selinexor)	Positive change	Add inclusion criteria: 2.Xpovio (Selinexor) may be used for relapsed/refractory multiple myeloma in combination with Bortezomib/Daratumumab +/- Dexamethasone in members who have received one prior therapy OR in combination with Pomalidomide +/- Dexamethasone following 2 prior lines of therapy including a proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib) and an immunomodulatory agent (e.g., lenalidomide, thalidomide, pomalidomide).	Per Compendia Listing
UM ONC_1365	Xpovio (selinexor)	Positive change	Remove inclusion criteria: A.Lack of documentation of disease progression on the drugs mentioned in the Inclusion Criteria.	NCH Pathway Expansion
UM ONC_1365	Xpovio (selinexor)	Negative change	Add exclusion criteria B.Dosing exceeds single dose limit of Xpovio (selinexor) 60 mg (for DBLCL) or 100 mg (for MM). C.Treatment exceeds the maximum limit of 20 (20 mg), 16 (40 mg), 8 (50 mg), 8 (60mg), ~~8 (80 mg) or 4 (100mg)~~ tablets/month.	FDA labeling
UM ONC_1367	Rozlytrek (entrectinib)	Positive change	Add inclusion criteria: B.NTRK-Fusion Positive Metastatic Solid Tumors a.The member has recurrent/metastatic/unresectable solid tumor (e.g., NSCLC) with a positive NTRK fusion in the tumor tissue (test confirmation required) AND Rozlytrek (entrectinib) will be used as a single agent as initial or subsequent therapy, if not previously used as initial treatment. b. ~~Member has experienced disease progression on standard/conventional systemic therapy.~~ C.Non-small cell lung cancer (NSCLC) 1.NOTE: The preferred agent, per NCH Policy and NCH Pathway, for first line therapy of ROS1 positive NSCLC with CNS metastases is Rozlytrek (entrectinib); for members without CNS metastases, the preferred agent is Zalkori (crizotinib). This recommendation is based on the lack of Level 1 evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes on rate of CNS progression with Zalkori (crizotinib) compared with Rozlytrek (entrectinib).. 2.The member has recurrent, advanced, or metastatic NSCLC and Rozlytrek (entrectinib) may be used as a single agent in members with any of the following: a.ROS-1 rearrangement-positive tumors with CNS metastases as first-line therapy, or with ROS-1 rearrangement with/without CNS metastases for subsequent line therapy following prior therapy with Xalkori (crizotinib) or Zykadia (ceritinib). ~~OR~~ b. ~~In members with NTRK gene fusion-positive tumors as subsequent therapy following progression on standard/conventional therapy (e.g., Chemotherapy, etc.).~~	Per Clinical Trial Analysis/Criteria
UM ONC_1367	Rozlytrek (entrectinib)	Negative change	Add exclusion criteria: D.Treatment exceeds the maximum limit of ~~30~~90 (100 mg) and 90~~60~~ (200 mg) tablets/month.	FDA labeling
UM ONC_1373	Endari (l-glutamine)	Positive change	Add inclusion criteria: B.Sickle Cell Disease 1.Endari (l-glutamine) may be used, with or without hydroxyurea, in members 5 years of age and older with Sickle Cell Disease (e.g., hemoglobin SS, HbS-beta0-thalassemia, and other related genotypes of Sickle Cell Disease) related complications, including pain crisis or acute chest syndrome, within the past 12 months.	FDA labeling
UM ONC_1373	Endari (l-glutamine)	Negative change	Add exclusion criteria: B.Dosing exceeds single dose limit of Endari (l-glutamine) 15 gm (equivalent to 3 packets).	FDA labeling
UM ONC_1375	Adakveo (crizanlizumab)	No Clinical Changes	N/A	N/A

Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
UM ONC_1376	Oxbryta (voxelotor)	Positive change	Add inclusion criteria: B.Sickle Cell Disease (including Homozygous Hemoglobin S, sickle Hemoglobin C disease, Hemoglobin S Beta-Thalassemia, or other genotypic variants of Sickle Cell Disease) 1.Oxbryta (voxelotor) may be used in members ~~12~~4 years of age and ol der with any of the above diagnoses, with a Hgb level of 5.5-10.5 gm/dL, prior therapy with hydroxyurea for 3 months, and a history of 1 or more vaso-occlusive crises in the past 12 months, Oxbryta (voxelotor) may be used with or without hydroxyurea.	New FDA Indication
UM ONC_1376	Oxbryta (voxelotor)	Negative change	Add exclusion criteria: A.The member continued to require blood transfusion or there was a lack of hemoglobin increase of at least 1gm/dL in the last 3 months.	FDA labeling
UM ONC_1379	Enhertu (fam-trastuzumab deruxtecan-nxki)	Positive change	Remove inclusion criteria: NOTE: Per NCH Pathway & NCH Policy, single agent Enhertu (fam-trastuzumab deruxtecan-nxki) is non-preferre d for the treatment of Head and Neck Cancers and Colorectal Cancer based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes compared to NCH preferred regimens. Please refer to NCH pathway for the preferred treatments in the above settings.	NCH Pathway Expansion
UM ONC_1379	Enhertu (fam-trastuzumab deruxtecan-nxki)	Positive change	Add inclusion criteria: 2.The member has experienced disease progression on ~~one~~2 or more prior regimens that included a fluoropyrimidine, a platinum agent, and trastuzumab	Per Compendia Listing
UM ONC_1379	Enhertu (fam-trastuzumab deruxtecan-nxki)	Negative change	Add exclusion criteria: B.Dosing exceeds single dose limit of Enhertu (fam-trastuzumab deruxtecan-nxki) 5.4 mg/kg (for breast cancer) and 6.4 mg/kg (for colorectal, gastric, esophageal, or GE junction cancer, or head and neck cancer).	FDA labeling
UM ONC_1393	Sarclisa (isatuximab-irfc)	Positive change	Remove inclusion criteria: B.Multiple Myeloma (MM) 1.NOTE: The preferred anti-CD38 agent, per NCH Policies, is Darzalex (daratumumab). This recommendation is based on a lack of Level 1 evidence (randomized trials and/or meta-analyses) showing superior patient outcomes with Sarclissa (isatuximab-irfc) vs Darzalex (daratumumab). Please see UM ONC_1280 Darzalex and Darzalex Faspro (daratumumab) policy. 2.NOTE: Sarclissa (isatuximab-irfc) use is NOT supported by NCH Policy for members with myeloma/plasma cell dyscrasia, who have experienced disease progression on prior therapy with Darzalex/Darzalex Faspro (daratumumab). 3.6.Sarclisa (isatuximab-irfc) may be used for members with relapsed or refractory MM ~~who have an intolerance or contraindication to Darzalex (daratumumab)~~and any of the following: a.Sarclisa (isatuximab-irfc) is being used in combination with Pomalyst (pomalidomide) and steroid AND the member ha s failed 2 ~~received~~ prior therapies with a proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib), and an immunomodulatory agent (e.g., lenalidomide, thalidomide) other than Pomalyst (pomalidomide) OR b.Sarclisa (isatuximab-irfc) is being used in combination with Kyprolis (carfilzomib) and steroid following 1 prior line of therapy other than Kyprolis (carfilzomib).	NCH Pathway Expansion
UM ONC_1401	Tukysa (tucatinib)	Negative change	Add inclusion criteria: NOTE: Per NCH Pathway & NCH Policy, Tukysa (tucatinib) is non-preferred in members with metastatic HER2 positive breast cancer, except in members with brain metastases. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior clinical outcomes with Tukysa (tucatinib) compared to another anti-HER2 based regimen. Please refer to NCH Pathway for the preferred treatments recommended for use in metastatic HER2 positive breast cancer. 1.Tukysa (tucatinib) may be used in members with metastatic HER2 positive breast cancer and brain metastases OR in members without brain metastases if there is disease progression on, contraindication, or intolerance to 3 or more prior anti HER-2 therapies in the metastatic setting including Kadcyla (ado- trastuzumab) and a trastuzumab containing regimen [e.g., Trastuzumab + Pertuzumab/Lapatinib +/- Chemotherapy] AND 2.Tukysa (tucatinib) will be used in combination with trastuzumab/trastuzumab biosimilar product (i.e., Kanjinti or Ogivri) and Xeloda (capecitabine). ~~1.Tukysa (tucatinib) may be used in combination with trastuzumab (i.e., Kanjinti or Ogivri) and Xeloda (capecitabine) in members with recurrent unresectable or metastatic HER-2 positive breast cancer, with or without brain metastases, following prior anti-HER2 based regimen(s) in the metastatic setting.~~	NCH Pathway Exclusion
UM ONC_1408	Zepzelca (lurbinectedin)	No Clinical Changes	N/A	N/A
UM ONC_1420	Margenza (margetuximab-cmkb)	Negative change	Remove inclusion criteria: B.Metastatic HER-2 + Breast Cancer 2.Margenza (margetuximab) may be used in combination with chemotherapy in members with metastatic HER-2+ breast cancer who have received prior therapy with at least 2 prior anti-HER2 therapies, at least one of which was for metastatic disease. Examples of prior anti-HER2 therapies include but are not limited to trastuzumab +/- chemotherapy, trastuzumab + pertuzumab +/- chemotherapy, and Kadcyla (ad-trastuzumab emtansine).	NCH Pathway Exclusion

Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
UM ONC_1422	Tepmetko (tepotinib)	Negative change	Add 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 mutations, confirmed by either tissue biopsy orf liquid biopsy (e.g., Guardant 360 or an equivalent FDA approved test), as initial or subsequent line therapy if was not used previously. 2.Members with asymptomatic brain metastases less than 1 cm or less in longest diameter and or members with treated brain metastases are also eligible to receive above therapy, provided their disease is positive for a MET exon 14 skipping mutations.	Per Compendia Listing
UM ONC_1423	Ukoniq (umbralisib)	Negative change	Add inclusion criteria: B.Marginal Zone Lymphoma 1.NOTE: In light of the FDA safety alert for the possible increased risk of death, Ukoniq (umbralisib) is not recommended for use in the treatment of Lymphomas. Please refer to NCH pathways for alternative therapies in the treatment of relapsed/refractory Marginal Zone Lymphoma. C.Follicular Lymphoma 1.NOTE: In light of the FDA safety alert for the possible increased risk of death, Ukoniq (umbralisib) is not recommended for use in the treatment of Lymphomas. Please refer to NCH pathways for alternative therapies in the treatment of relapsed/refractory Follicular Lymphooma.	FDA safety alert
UM ONC_1423	Ukoniq (umbralisib)	Negative change	Remove inclusion criteria: B.Marginal Zone Lymphoma 1.Ukoniq (umbralisib) may be used as monotherapy for members with Marginal Zone Lymphoma, who have received (and progressed on or after) at least one prior regimen that included an anti-CD20 antibody (e.g., rituximab/biosimilars). C.Follicular Lymphoma 1.Ukoniq (umbralisib) may be used as monotherapy for members with Follicular Lymphoma, who have received (and progressed on or after) at least 3 prior lines of therapy, including one regimen that included an anti-CD20 antibody (e.g., rituximab/biosimilars).	FDA safety alert
UM ONC_1433	Jemperli (dostarlimab-gxly)	Positive change	Remove inclusion criteria: B.Endometrial Carcinoma 1.NOTE: The preferred immunotherapy-per NCH Policy- for dMMR/MSI-High, recurrent, or advanced/metastatic endometrial carcinoma, that has progressed on prior platinum chemotherapy is Keytruda (pembrolizumab). This recommendation is based on a lack of level 1 evidence (randomized trial and/or meta-analysis) showing superior efficacy of Jemperli (dostarlimab-gxly) over Keytruda (pembrolizumab). Please see UM ONC_1263 Keytruda (pembrolizumab) policy. C.Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumors 1.NOTE: Per NCH policy, the preferred immunotherapy for recurrent, advanced, or metastatic MSI-H/dMMR solid tumors is Keytruda (pembrolizumab). This recommendation is based on a lack of level 1 evidence (randomized trials and/or meta-analyses) showing superior efficacy of Jemperli (dostarlimab-gxly) over Keytruda (pembrolizumab). Please see UM ONC_1263 Keytruda (pembrolizumab) policy.	NCH Pathway Expansion