Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
New	Lytgobi (futibatinib)	N/A	N/A	N/A
New	Pedmark (sodium thiosulfate)	N/A	N/A	N/A
UM ONC_1028	Bevacizumab Products	Positive change	Add inclusion criteria: Add new product for Vegzelma (bevacizumab-adcd)	New FDA Indication
UM ONC_1028	Bevacizumab Products	Negative change	Remove inclusion criteria: C.Colorectal Cancer a.As initial therapy in combination with capecitabine or with FOLFOX, FOLFIRI, ~~FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan),~~ FOLFIRINOX (fluorouracil, leucovorin, irinotecan, and oxaliplatin), 5-FU/LV (fluorouracil and leucovorin), or CapeOX (capecitabine and oxaliplatin).	Per Compendia Listing
UM ONC_1028	Bevacizumab Products	Negative change	Add inclusion criteria: D.Non-Small Cell Lung Cancer (NSCLC) 1.Bevacizumab based regimens are non-preferred for metastatic Non-Small Cell Lung Cancer with the following exception: For first/initial line therapy for members with recurrent/metastatic non-squamous Non-Small Cell Lung Cancer as a part of [carboplatin + paclitaxel+ bevacizumab+ atezolizumab] followed by maintenance atezolizumab ± bevacizumab; above regimen not supported if member has experienced disease progression on prior Immune Checkpoint Inhibitor therapy . 2.NOTE: Per NCH Pathway & NCH Policy, Policy, regimens containing [bevacizumab/bevacizumab biosimilar + platinum-based chemotherapy] are non-preferred for all lines of therapy with the exception noted above. This position is based on the finding of increased risk of serious adverse effects and marginal PFS and OS benefit in randomized trials (e.g., a 2 month OS benefit and a 1.3 month PFS benefit with 15 treatment related deaths in the bevacizumab arm including 5 from pulmonary hemorrhage-ECOG trial Sandler et al N Engl J Med 12-14-2006) . Alternative agents/regimens recommended by NCH can be found at : http://pathway.newcenturyhealth.com. F.Renal Cell Carcinoma NOTE: Per NCH Policy, the use of bevacizumab/bevacizumab biosimilar as monotherapy or in combination with other anti-cancer agent is non-preferred in the treatment of RCC. 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)/bevacizumab biosimilar compared to alternative agents/regimens recommended by NCH Policy and NCH Pathways (http://pathways.newcenturyhealth.com). G.Cervical Cancer 3.NOTE: Per NCH policy, Bevacizumab + Pembrolizumab + cisplatin/carboplatin + paclitaxel is a non-preferred regimen for initial treatment of PD-L1 positive metastatic cervical cancer. This recommendation is based on the results of a randomized trial by Colombo et al referenced below that showed no additional benefit of adding bevacizumab to [platinum+paclitaxel+pembrolizumab] in PD-L1 + patient with metastatic/recurrent/inoperable cervical carcinoma	Per NCH Pathway exclusion AND expansion
UM ONC_1028	Bevacizumab Products	Negative change	Remove inclusion criteria: 1.The member has locally advanced, recurrent, or metastatic non-squamous non-small cell lung cancer and bevacizumab/bevacizumab biosimilar will be used as first line therapy in combination with carboplatin and paclitaxel. NOTE: Per NCH Pathway & NCH Policy, regimens containing [bevacizumab/bevacizumab biosimilar + platinum-based chemotherapy] are Non-Preferred per NCH Policy & NCH Pathway for locally advanced, recurrent, or metastatic non-squamous Non-Small Cell Lung Cancer ((Exception: Carboplatin + Paclitaxel + Bevacizumab + Atezolizumab followed by maintenance Bevacizumab + Atezolizumab). This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superiority of bevacizumab containing regimens compared to NCH preferred regimens, in the first or subsequent line settings. Please refer to the NCH Pathway document for the current recommended regimens in the above cancer type/stage.	Per NCH Pathway exclusion AND expansion
UM ONC_1072	Myeloid Growth Factors	Positive change	Add inclusion criteria: Added Intermediate risk table and updates to Low and High risk tables	Per Compendia Listing
UM ONC_1130	Alimta or Pemfexy (pemetrexed)	Negative change	Add inclusion criteria: 2. 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) demonstrating superior outcomes compared to NCH recommended alternatives agents/regimens, including but not limited to regimens at http://pathways.newcenturyhealth.com. b.Nivolumab + Ipilimumab + Carboplatin/Cisplatin + Pemetrexed followed by maintenance Nivolumab + Ipilimumab (for PD-L1 greater than or equal to 50%). 3.NOTE: Per NCH Policy, the use of J9305 pemetrexed is preferred over J9304 Pemfexy (pemetrexed) for all clinical settings where Alimta/Pemfexy is indicated. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with one pemetrexed product over another. C.Malignant Pleural Mesothelioma 2.NOTE: Per NCH Policy, the use of J9305 pemetrexed is preferred over J9304 Pemfexy (pemetrexed) for all clinical settings where Alimta/Pemfexy is indicated. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with one pemetrexed product over another.	Per NCH Pathway exclusion
UM ONC_1179	Abraxane (nab-paclitaxel)	Negative change	Add inclusion criteria: Cervical Cancer, Endometrial Cancer, and Ovarian Cancer 1.NOTE: Per NCH Policy, the use of Abraxane (albumin-bound paclitaxel) is non-preferred for the treatment of cervical cancer, endometrial cancer, and ovarian cancer. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with Abraxane (albumin-bound paclitaxel) compared to Taxol(paclitaxel) or Taxotere (docetaxel). Abraxane use is supported if the member has there is a history of a severe allergic reaction/anaphylaxis to solvent-based Taxol (paclitaxel) or Taxotere (docetaxel).	Per NCH Pathway exclusion
UM ONC_1194	Nexavar (sorafenib)	Negative change	Add inclusion criteria: 1.NOTE: Per NCH Pathway & NCH Policy, Nexavar (sorafenib) is a Non-Preferred regimen as subsequent treatment for recurrent/metastatic RCC. This recommendation is 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 recommended alternatives agents/regimens, including but not limited to regimens at http://pathways.newcenturyhealth.com.	Per NCH Pathway exclusion
UM ONC_1194	Nexavar (sorafenib)	Positive change	Remove inclusion criteria: B.Renal Cell Carcinoma (RCC) 1.Nexavar (sorafenib) may be used as a single agent for recurrent or metastatic RCC in members who have disease progression, contraindications, or intolerance to prior Votrient (pazopanib) AND Cabometyx (cabozantinib). C.Hepatocellular Carcinoma (HCC) 2.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.	Per NCH Pathway expansion
UM ONC_1194	Nexavar (sorafenib)	Positive change	Remove inclusion criteria: C.Hepatocellular Carcinoma (HCC) 1.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).~~	Per NCH Pathway expansion
UM ONC_1197	Sutent (sunitnib)	Positive change	Remove inclusion criteria: B.Renal cell carcinoma (RCC) 1.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, have a contraindication to, or disease progression on Votrient (pazopanib).~~ ~~2.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.~~	Per NCH Pathway expansion

UM ONC_1201	Yervoy (ipilimumab)	Positive change	Remove inclusion criteria: B.Melanoma 1.NOTE: The preferred drugs, per NCH Policies & NCH Pathway, for the adjuvant therapy of completely resected stage III melanoma are Opdivo (nivolumab) OR Keytruda (pembrolizumab). Please refer to UM ONC_1274 Opdivo (nivolumab) policy or UM ONC_1263 Keytruda (pembrolizumab) policy. Adjuvant Yervoy (ipilimumab) + Opdivo (nivolumab) is not recommended in this setting. This recommendation is based on randomized data showing inferior outcomes with Yervoy (ipilimumab) + Opdivo (nivolumab) compared to single agent Opdivo (nivolumab) or single agent Keytruda (pembrolizumab). F.Non-Small Cell Lung Cancer 1.Squamous and Non-Squamous metastatic Non-Small Cell Lung Cancer with PD-L1 ≤1 %: Yervoy (ipilimumab) + Opdivo (nivolumab) may be used in metastatic Non- Small Cell Lung Cancer (both squamous and non-squamous) that is EGFR and ALK negative and has a PDL-1 expression <1% OR 2.Non- Squamous metastatic Non-Small Cell Lung Cancer with PD-L1= 1-49%: Yervoy (ipilimumab) + Opdivo (nivolumab) may be used without platinum + Alimta (pemetrexed) for non-squamous metastatic Non-Small Cell Lung Cancer that is EGFR and ALK negative and has a PDL-1 expression of 1-49% 3.NOTE 1: 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 Yervoy (ipilimumab) + Opdivo (nivolumab) is superior compared to NCH Preferred regimens. Please refer to NCH Pathway for the preferred treatments recommended for metastatic NSCLC: a.Yervoy (ipilimumab) + Opdivo (nivolumab)- with or without platinum + paclitaxel- is a non-Preferred regimen for metastatic squamous Non-Small Cell Lung Cancer that has a PDL-1 expression of ≥1%. The preferred regimen in this setting is pembrolizumab + Carboplatin + Paclitaxel as first line therapy followed by single agent Pembrolizumab as maintenance or subsequent therapy. b.Yervoy (ipilimumab) + Opdivo (nivolumab)with or without chemotherapy is a non-Preferred regimen for metastatic squamous or non-squamous Non-Small Cell Lung Cancer, that is EGFR and ALK negative and have a PDL-1 expression of ≥ 50%. The preferred agents in this setting are single agent Keytruda (pembrolizumab), single agent Libtayo (cemiplimab), or single agent Tecentriq (atezolizumab).	Per NCH Pathway expansion
UM ONC_1201	Yervoy (ipilimumab)	Negative change	Add inclusion criteria: F.Non-Small Cell Lung Cancer 2.Yervoy (ipilimumab) + Opdivo (nivolumab) +/- Carboplatin + Paclitaxel may be used as first line treatment for squamous metastatic Non- Small Cell Lung Cancer that is EGFR and ALK negative and has a PDL-1 expression less than 50% OR 3.Yervoy (ipilimumab) + Opdivo (nivolumab) + Cisplatin/Carboplatin + Alimta (pemetrexed) for first line non-squamous metastatic Non-Small Cell Lung Cancer that is EGFR and ALK negative and has a PDL-1 expression less than 50%. 4.NOTE: Per NCH Policy, Opdivo (nivolumab) + Yervoy (ipilimumab) in combination with +/-Chemotherapy is a non-Preferred regimen for metastatic squamous and non-squamous Non-Small Cell Lung Cancer, for PDL-1 greater than or equal to 50%. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with Opdivo (nivolumab) + Yervoy (ipilimumab) in combination with +/- Chemotherapy compared to NCH recommended alternatives agents/regimens, including but not limited to regimens at http://pathways.newcenturyhealth.com	Per NCH Pathway exclusion
UM ONC_1219	Jevtana (cabazitaxel)	Positive change	Remove inclusion criteria: B.Prostate Cancer 1.NOTE: The preferred dose of Jevtana for NCH Policy is 20 mg/m2 IV every 3 weeks. This dose is associated with a lower risk for febrile neutropenia and a lower incidence of clinically significant ADRs than 25 mg/m2 IV every 3 weeks.	Per NCH Pathway expansion
UM ONC_1219	Jevtana (cabazitaxel)	Negative change	Add inclusion criteria: B.Prostate Cancer 1.The member has evidence of a diagnosis of castration-resistant distant metastatic (M1) disease and has experienced disease progression on docetaxel therapy and androgen receptor inhibitor (e.g., abiraterone, enzalutamide) AND 2. Jevtana (cabazitaxel) will be used in combination with a steroid + LHRH analog/orchiectomy as a form of androgen deprivation therapy (ADT) .	Per Clinical Trial Analysis/Criteria
UM ONC_1219	Jevtana (cabazitaxel)	Negative change	Add exclusion criteria: A.Disease progression while on Jevtana (cabazitaxel). A.B.Dosing exceeds single dose limit of Jevtana (cabazitaxel) 25 ~~0~~ mg/m2.	Per Clinical Trial Analysis/Criteria
UM ONC_1222	Erivedge (vismodegib)	No Clinical Changes	N/A	N/A
UM ONC_1223	Inlyta (axitinib)	Positive change	Remove inclusion criteria: B.Renal Cell Carcinoma (RCC) 7.NOTE 1: The preferred agents, per NCH Policy and NCH Pathway, for first line metastatic disease are: Votrient (pazopanib) for IMDC Good Risk Disease and Cabometyx (cabozantinib) or [Yervoy (ipilimumab) + Opdivo (nivolumab)] for IMDC Intermediate & Poor Risk Disease. 7.NOTE 2: Inlyta (axitinib) + Keytruda (pembrolizumab) is a non-preferred regimen for the first line setting for metastatic renal cell carcinoma due to the lack of Level 1 evidence showing superiority of Inlyta (axitinib) + Keytruda (pembrolizumab)/Bavencio (avelumab) over [Yervoy (ipilimumab) + Opdivo (nivolumab)] in IMDC Intermediate & Poor Risk disease. 2.Inlyta (axitinib) may be used as a single agent after failure of one prior systemic therapy in members with relapsed, medically unresectable, advanced, or metastatic renal cell carcinoma.	Per NCH Pathway expansion
UM ONC_1223	Inlyta (axitinib)	Positive change	Add inclusion criteria: B.Renal Cell Carcinoma (RCC) 1.Inlyta (axitinib) may be used in combination with Keytruda (pembrolizumab) as first line treatment for recurrent or metastatic metastatic, IMDC favorable/intermediate/poor risk renal cell carcinoma.	Per Clinical Trial Analysis/Criteria
UM ONC_1223	Inlyta (axitinib)	Negative change	Add inclusion criteria: B.Renal Cell Carcinoma (RCC) 2.NOTE 1: Per NCH Policy, the use of Inlyta (axitinib) in RCC is non-Preferred in the following clinical settings: a.First line, favorable/intermediate/poor risk clear cell RCC: single agent Inlyta (axitinib) b.Subsequent line clear cell RCC: Inlyta (axitinib) + Bavencio (avelumab). c.Above position is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes compared to NCH recommended alternatives agents/regimens, including but not limited to regimens at http://pathways.newcenturyhealth.com	Per NCH Pathway exclusion
UM ONC_1223	Inlyta (axitinib)	Positive change	Remove exclusion criteria: B.Inlyta (axitinib) is being used concurrently with anti-cancer therapy. C.Treatment with Inlyta (axitinib) exceeds the maximum limit of ~~60~~180 (1mg) tablets or 120 (5mg) tablets a month.	Per FDA labeling
UM ONC_1227	Zolinza (vorinostat)	Negative change	Add inclusion criteria: B.Cutaneous T-Cell Lymphoma (CTCL) 1. Treatment of cutaneous manifestations in patients with cutaneous T-cell lymphoma (CTCL) who have progressive, persistent or recurrent disease on or following two systemic therapies	Per Compendia Listing
UM ONC_1227	Zolinza (vorinostat)	Negative change	Remove inclusion criteria: B.Cutaneous T-Cell Lymphoma (CTCL) The member has relapsed/refractory stage IIB-IV CTCL (including mycosis fungoides or Sezary syndrome) AND Zolinza (vorinostat) will be used as monotherapy .	Per Compendia Listing

UM ONC_1230	Istodax (romidepsin)	Positive change	Add inclusion criteria: B.Cutaneous T-Cell Lymphomas (CTCL) 1.Treatment of cutaneous T-cell lymphoma (CTCL) in patients who have received at least one prior systemic	Per Compendia Listing
UM ONC_1230	Istodax (romidepsin)	Positive change	Remove inclusion criteria: B.Cutaneous T-Cell Lymphomas (CTCL) The member has relapsed/refractory stage IIB-IV CTCL (all subtypes including mycosis fungoides andor Sezary syndrome) and Istodax (romidepsin) is being used as monotherapy following one prior systemic therapy (e.g., bexarotene, vorinostat).	Per Compendia Listing
UM ONC_1230	Istodax (romidepsin)	Positive change	Add exclusion criteria: B.Concurrent use with other chemotherapy. Istodax (romidepsin) may be used with skin directed therapy or radiation therapy.	Per Compendia Listing
UM ONC_1231	Marqibo (vincristine liposome)	Negative change	Add inclusion criteria: B.Acute Lymphoblastic Leukemia (ALL) 1.NOTE: Per NCH policy, Marqibo (vincristine liposome) is not preferred or supported by the FDA as an appropriate therapeutic agent for relapsed/refractory ALL. This recommendation is based on the voluntary withdrawal by the manufacturer due to a lack of patient recruitment in the confirmatory clinical trial to verify clinical benefit; therefore, the FDA withdrew the approval of Marqibo (vincristine liposome) on May 2, 2022. Please refer to NCH recommended alternatives agents/regimens, including but not limited to regimens at http://pathways.newcenturyhealth.com	Per NCH Pathway exclusion
UM ONC_1231	Marqibo (vincristine liposome)	Positive change	Remove inclusion criteria: B.Acute Lymphoblastic Leukemia (ALL) 1.The member has relapsed disease and has progressed after 2 or more lines of anti-leukemic therapy including a Tyrosine Kinase Inhibitor (for Philadelphia Chromosome + ALL only) AND 2.Marqibo (vincristine liposome) is being used as a single agent.	Per NCH Pathway expansion
UM ONC_1235	Doxil (liposomal doxorubicin)	Positive change	Remove inclusion criteria: B.NOTE: The preferred agent, per NCH Policies, is standard Doxorubicin (Adriamycin) when used for Hodgkin lymphoma and breast cancer, Doxil (liposomal doxorubicin) is non-preferred in the above settings.	Per NCH Pathway expansion
UM ONC_1235	Doxil (liposomal doxorubicin)	Negative change	Add inclusion criteria: D.Breast Cancer 1.NOTE: Per NCH Policy, Doxil (liposomal doxorubicin) is non-preferred for the treatment of recurrent, unresectable, or 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 Doxil (liposomal doxorubicin) compared to conventional formulation of doxorubicin (e.g., Adriamycin)	Per NCH Pathway exclusion
UM ONC_1259	Gazyva (obinutuzumab)	Positive change	Remove inclusion criteria: C.Follicular Lymphoma 2.NOTE: Per NCH Pathway & NCH Policy, Lenalidomide + Obinutuzumab is a non-Preferred regimen for initial treatment of Follicular Lymphoma. 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. Please refer to NCH Pathway for the alternative treatments recommended for use in Follicular Lymphoma.	Per NCH Pathway expansion
UM ONC_1265	Zykadia (ceritinib)	Positive change	Remove inclusion criteria: B.Non-Small Cell Lung Cancer ~~1.NOTE: The preferred agent, per NCH Policy and NCH Pathways, for first line therapy of metastatic ALK+ NSCLC is Alecensa (alectinib). This recommendation is based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) that shows superior outcomes with Zykadia (ceritinib) over Alecensa (alectinib). Please refer to UMC ONC_1277 Alecensa (alectinib) policy.~~ 2.Zykadia (ceritinib) may be used as monotherapy for first line or subsequent therapy of ALK + rearrangement positive metastatic NSCLC ~~if the member is intolerant/has a contraindication to Alecensa (alectinib) OR~~ ~~3.Zykadia (ceritinib) may be used as monotherapy for second line or subsequent therapy for ALK+ metastatic NSCLC if the member has experienced disease progression on Alecensa (alectinib), Xalkori (crizotinib), Lorbrena (lorlatinib), or Alunbrig (brigatinib).~~	Per NCH Pathway expansion
UM ONC_1265	Zykadia (ceritinib)	Negative change	Add exclusion criteria: A.Disease progression while taking Zykadia (ceritinib). B.Lack of documentation for the detection of ALK rearrangement by an FDA approved test; a list of the FDA approved test is available at www.fda.gov/CompanionDiagnostics.	Per FDA labeling
UM ONC_1274	Opdivo (nivolumab)	Positive change	Remove inclusion criteria: C.Non-Small Cell Lung Cancer (NSCLC) 3.Squamous & Non-Squamous metastatic Non-Small Cell Lung Cancer with PD-L1 of ≤ 1%: Opdivo (nivolumab) + Yervoy (ipilimumab) may be used in metastatic Non- Small Cell Lung Cancer (both squamous and non-squamous) that is EGFR and ALK negative and has a PDL-1 expression <1% OR Non-squamous metastatic Non-Small Cell Lung Cancer with PD-L1= 1-49% : Opdivo (nivolumab) + Yervoy (ipilimumab) may be used without platinum + pemetrexedAlimta (pemetrexed) for non-squamous metastatic Non-Small Cell Lung Cancer that is EGFR and ALK negative and has a PDL-1 expression of 1-49% 4.Squamous metastatic Non-Small Cell Lung Cancer with PD-L1= 1-49 % : 3.in combination with platinum + pemetrexedin combination with platinum +pemetrexed evidence-based 5.NOTE 1: 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 Opdivo (nivolumab) + Yervoy (ipilimumab) is superior compared to NCH Preferred regimens. Please refer to NCH Pathway for the preferred treatments recommended for metastatic NSCLC: 6.Opdivo (nivolumab) + Yervoy (ipilimumab) - with or without platinum + paclitaxel- is a non-Preferred regimen for metastatic squamous Non-Small Cell Lung Cancer that has a PDL-1 expression of ≥1%. The preferred regimen in this setting is pembrolizumab + Carboplatin + Paclitaxel as first line therapy followed by single agent Pembrolizumab as maintenance or subsequent therapy. 7.Opdivo (nivolumab) + Yervoy (ipilimumab) with or without chemotherapy is a non-Preferred regimen for metastatic squamous or non-squamous Non-Small Cell Lung Cancer, that is EGFR and ALK negative and have a PDL-1 expression of ≥ 50%. The preferred agents in this setting are single agent Keytruda (pembrolizumab), single agent Libtayo (cemiplimab), or single agent Tecentriq (atezolizumab). D.Renal Cell Carcinoma 2.NOTE: First line therapy with [Cabometyx (cabozantinib) + Opdiv o (nivolumab)] for advanced/metastatic clear cell Renal Cell Carcinoma is not recommended per NCH Policy or NCH Pathway. This position is based on the following: a.Our detailed review of the CheckMate9ER trial showed that the HR for OS for IMDC Favorable Risk disease was 0.84, with wide Confidence Intervals that crossed 1.0 (CI 0.35-1.97). The HR for PFS for IMDC Favorable Risk disease was 0.62, however, again the Confidence Intervals were wide and crossed 1.0 (CI 0.38-1.01). a.For IMDC Intermediate and Poor risk disease, there is a lack of Level 1 evidence (randomized trials and/or meta-analysis) to support the superiority of [Cabometyx (cabozantinib) + Opdivo (nivolumab)] over [Opdivo (nivolumab) + Yervoy (ipilimumab)]- the recommended regimen per NCH Policy and NCH Pathway. b.Additionally, for IMDC Intermediate and Poor Risk disease, Cabometyx (cabozantinib) has already been shown to be superior to Sutent (sunitinib) per the CABOSUN trial. Therefore, the control arm- in the CheckMate9ER trial- with single agent Sutent (sunitinib) is not optimal/standard.	Per NCH Pathway expansion

UM ONC_1275	Opdivo (nivolumab)	Negative change	Add inclusion criteria: 1.Yervoy (ipilimumab) + Opdivo (nivolumab) +/- Carboplatin + Paclitaxel may be used as first line treatment for squamous metastatic Non- Small Cell Lung Cancer that is EGFR and ALK negative and has a PDL-1 expression less than 50% OR 2.Yervoy (ipilimumab) + Opdivo (nivolumab) +/- Cisplatin/Carboplatin + Alimta (pemetrexed) may be used for first line non-squamous metastatic Non-Small Cell Lung Cancer that is EGFR and ALK negative and has a PDL-1 expression less than 50%. 3.NOTE: Per NCH Policy, Opdivo (nivolumab) + Yervoy (ipilimumab) +/- Chemotherapy is a non-Preferred regimen for metastatic non-squamous and squamous Non-Small Cell Lung Cancer, for PDL-1 greater than or equal to 50%. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with Opdivo (nivolumab) + Yervoy (ipilimumab) +/- Chemotherapy compared to NCH alternative agents/regimens, including but not limited to regimens at http://pathways.newcenturyhealth.com. H.Colorectal Cancer 4.NOTE: Per NCH Pathway & NCH Policy, Opdivo (nivolumab) + Yervoy (ipilimumab) is a non-Preferred regimen for the treatment of metastatic MSI-High colorectal cancer. 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 recommended alternatives agents/regimens, including but not limited to regimens at http://pathways.newcenturyhealth.com.	Per NCH Pathway exclusion
UM ONC_1276	Onivyde (irinotecan liposome injection)	Positive change	Remove and add inclusion criteria: B.Metastatic Adenocarcinoma of the Pancreas and Ampullary Adenocarcinoma 1.Oniyvide (irinotecan liposome) may be used for members with recurrent/metastatic pancreas cancer adenocarcinoma of the pancreas or ampullary adenocarcinoma who have progressed on prior therapy with both a gemcitabine-based regimen (e.g., gemcitabine +/- nab-paclitaxel) ~~AND FOLFIRINOX (except when patient was felt to be unfit for this regimen)~~	Per Clinical Trial Analysis/Criteria
UM ONC_1281	Empliciti (elotuzumab)	No Clinical Changes	N/A	N/A
UM ONC_1297	Venclexta (venetoclax)	Positive change	Add inclusion criteria: B.Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) 1.Venclexta (venetoclax) may be used in combination with Gazyva (obinutuzumab) as first or subsequent line the rapy OR as a single agent with or without rituximab/rituximab biosimilar product as subsequent line therapy for the treatment of CLL/SLL .	Per Compendia Listing
UM ONC_1297	Venclexta (venetoclax)	Positive change	Remove inclusion criteria: B.Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) 2.NOTE: Per NCH Policy & NCH Pathway, the combination of Venclexta (venetoclax) +/- rituximab/rituximab biosimilar product 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) + Gazyva (obinutuzumab). Please refer to NCH pathway for the preferred treatments in CLL/SLL. D.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.~~	Per NCH Pathway expansion
UM ONC_1306	Bavencio (avelumab)	Positive change	Add inclusion criteria: C. Urothelial Carcinoma including carcinomas of the upper Genito-Urinary Tract & Urethra 1.Bavencio (avelumab) may be used as a single agent, as second line/subsequent therapy following prior platinum-based chemotherapy, and in a member with locally advanced or metastatic urothelial carcinoma including the upper genito-urinary tract/urethra OR. 2. ~~Maintenance Therapy after systemic chemotherapy.~~ Member has locally advanced or metastatic urothelial carcinoma, including carcinoma of the upper genito-urinary tract/urethra, and has experienced CR/PR/SD with 4-6 cycles of first line platinum (cisplatin/carboplatin) containing chemotherapy AND Bavencio (avelumab) is being used as a single agent maintenance therapy following the above first line platinum containing chemotherapy. D.Renal Cell Carcinoma (RCC) 1.Bavencio (avelumab) may be used in combination with Inlyta (axitinib) as first line therapy in members with advanced/metastatic RCC.	Per FDA labeling
UM ONC_1306	Bavencio (avelumab)	Positive change	Remove inclusion criteria: D.Renal Cell Carcinoma (RCC) 1.2.NOTE: Bavencio (avelumab) + Inlyta (axitinib) is a non-preferred regimen for subsequent treatment of advanced or metastatic renal cell carcinoma per NCH Policy. ~~& NCH Pathway. Opdivo (nivolumab), given as a single agent or in combination with 4 cycles of Ipilimumab at 1mg/kg, is the preferred agent/regimen over other regimens containing PD-1 or PD-L1 inhibitors (e.g. [Avelumab + Axitinib] & [Pembrolizumab + Axitinib]) for metastatic renal cell carcinoma.~~ This recommendation is based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) to show superior outcomes with Bavencio (avelumab) + Inlyta(axitinib) in the subsequent line setting + Inlyta (axitinib) compared to NCH preferred first line regimen. NCH recommended alternatives agents/regimens, including but not limited to regimens at http://pathways.newcenturyhealth.com.	Per NCH Pathway exclusion
UM ONC_1306	Bavencio (avelumab)	Negative change	Add exclusion criteria: B.Dosing exceeds single dose limit of Bavencio (avelumab) ~~10mg/kg~~ 800 mg.	Per FDA labeling
UM ONC_1309	Iressa (gefitinib)	Positive change	Remove inclusion criteria: B.Non-Small Cell Lung Cancer (NSCLC) 1.NOTE: NCH policy & NCH Pathway, Iressa (gefitinib) is a non-Preferred drug for first line therapy of recurrent/metastatic EGFR mutation positive Non-Small Cell Lung Cancer. The preferred treatment in the above setting is Tagrisso (osimertinib). This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show Iressa (gefitinib) is superior to Tagrisso (osimertinib). Please see UM ONC_1287 Tagrisso (osimertinib) policy.	Per NCH Pathway expansion
UM ONC_1309	Iressa (gefitinib)	Positive change	Remove inclusion criteria: B.Non-Small Cell Lung Cancer (NSCLC) 2.Iressa (gefitinib) may be used as a single agent in members with a known EGFR exon 19 deletions or exon 21 (L858R) sensitizing mutation as initial or subsequent line therapy. ~~as subsequent line therapy for recurrent or metastatic NSCLC. Iressa (gefitinib) may be used as first line therapy in a member who has a contraindication/intolerance to Tagrisso (osimertinib)~~	Per Compendia Listing
UM ONC_1344	Poteligeo (mogamulizumab-kpkc)	Positive change	Remove inclusion criteria: B.Mycosis Fungoides/Sezary Syndrome 1.Poteligeo (mogamulizumab-kpkc) may be will be used as a single agent for adult patients with relapsed or refractory mycosis fungoides or Sézary syndrome after at least one prior systemic therapy ~~relapsed or refractory stage IIB-IV mycosis fungoides/Sezary syndrome and after at least one systemic therapy (e.g., bexarotene, romidepsin)~~	Per Compendia Listing
UM ONC_1347	Lorbrena (lorlatinib)	Positive change	Remove inclusion criteria: B.Non-Small Cell Lung Cancer (NSCLC) 1.Lorbrena (lorlatinib) may be used as monotherapy in members with recurrent or metastatic ALK positive NSCLC, as initial or subsequent therapy ~~as subsequent therapy. This recommendation is based on an improved median PFS, ORR, and DOR with Lorbrena (lorlatinib) when compared to Xalkori (crizotinib) in the above setting.~~ ~~2.NOTE: Per NCH Pathway & NCH Policy, Lorbrena (lorlatinib) is a non-Preferred drug for the initial treatment of anaplastic lymphoma kinase (ALK) positive NSCLC. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior clinical outcomes with Lorbrena (lorlatinib) compared to NCH Preferred regimens. Preferred first line agents are Alecensa (alectinib) or Alunbrig (brigatinib).~~	Per NCH Pathway expansion
UM ONC_1379	Enhertu (fam-trastuzumab deruxtecan-nxki)	Positive change	Add inclusion criteria: C.HER-2 positive, metastatic/recurrent Gastric, Esophageal and GE Junction adenocarcinoma 1.The member has metastatic/recurrent, HER-2 positive Gastric, Esophageal or GE Junction adenocarcinoma AND 2.The member has experienced disease progression on a prior regimen that included trastuzumab/trastuzumab biosimilar	Per FDA labeling

UM ONC_1379	Enhertu (fam-trastuzumab deruxtecan-nxki)	Positive change	Remove inclusion criteria: C.HER-2 positive, metastatic/recurrent Gastric, Esophageal and GE Junction adenocarcinoma 1.The member has metastatic/recurrent, HER-2 positive Gastric, Esophageal or GE Junction adenocarcinoma AND 2. ~~The member has experienced disease progression on one or more prior regimens that included a fluoropyrimidine [i.e., fluorouracil/capecitabine], a platinum agent (i.e., cisplatin/carboplatin/oxaliplatin), and if there were no contraindications/intolerance to prior Herceptin (trastuzumab)/trastuzumab biosimilar product~~	Per FDA labeling
UM ONC_1379	Enhertu (fam-trastuzumab deruxtecan-nxki)	Negative change	Add exclusion criteria: B.For HER-2 positive Gastric, Esophageal and GE Junction adenocarcinoma: Use of Enhertu (fam-trastuzumab deruxtecan-nxki) without receiving prior trastuzumab treatment	Per FDA labeling
UM ONC_1384	Targretin (bexarotene)	Positive change	Remove inclusion criteria: B.Cutaneous T-Cell Lymphoma (CTCL) 1. The member has relapsed/refractory stage IIB-IV cutaneous T-cell lymphoma (all variants) or mycosis fungoides/Sezary syndrome AND 2.The member is refractory or intolerant to at least 2 prior therapies AND 3.Targretin (oral bexarotene) is being used as a single agent.	Per Compendia Listing
UM ONC_1384	Targretin (bexarotene)	Positive change	Add inclusion criteria: B.Cutaneous T-Cell Lymphoma (CTCL) 1.Targretin (bexarotene) capsules are indicated for the treatment of cutaneous manifestations of cutaneous T-cell lymphoma in patients who are refractory to at least one prior systemic therapy.	Per Compendia Listing
UM ONC_1384	Targretin (bexarotene)	Positive change	Remove exclusion criteria: B. Concurrent use with other chemotherapy. Targretin (oral bexarotene) may be used with skin directed therapy or radiation therapy.	Per Compendia Listing
UM ONC_1391	Thalomid (thalidomide)	Negative change	Add inclusion criteria: B.Multiple Myeloma 1.The member has multiple myeloma and Thalomid (thalidomide) is being used in any as ONE of the following clinical situations: a. In combination with Velcade (bortezomib) + Dexamethasone +/- Darzalex/Darzalex Faspro (daratumumab) as primary/initial line of therapy for transplant-eligible newly diagnosed multiple myeloma ~~candidate~~ OR b.As a part of In VTD-PACE (bortezomib, dexamethasone, thalidomide, cisplatin, doxorubicin, cyclophosphamide, and etoposide) regimen for relapsed/refractory myeloma as initial reinduction therapy for disease relapse > 6 months or as subsequent line of therapy OR c.In DT-PACE (dexamethasone, thalidomide, cisplatin, doxorubicin, cyclophosphamide, and etoposide) regimen for relapsed/refractory myeloma.	Per Compendia Listing
UM ONC_1391	Thalomid (thalidomide)	Negative change	Add exclusion criteria: B.Member has disease progression ~~while taking~~ on or after taking Thalomid (thalidomide). C.Dosing exceeds single dose limit of Thalomid (thalidomide) 120 (50 mg), 60 (100 mg), 30 (150 mg), 30 (200 mg) capsules/month.	Per FDA labeling
UM ONC_1405	Retevmo (selpercatinib)	Positive change	Add inclusion criteria: D.Metastatic Solid Tumors with a RET Gene Fusion 1.Retevmo (selpercatinib) may be used as monotherapy in a member with recurrent unresectable or metastatic solid tumor, is positive for RET Gene Fusion detected by an FDA approved test, and the disease has progressed following one or more prior systemic therapies.	New FDA Indication
UM ONC_1405	Retevmo (selpercatinib)	Negative change	Add exclusion criteria: D.Dosing exceeds single dose limit of Retevmo (selpercatinib) 120 mg (for weight < 50 kg) or 160 mg (for weight ≥ 50kg). E.Treatment exceeds the maximum limit of ~~180~~240 (40 mg) or 120 (80 mg) ~~tablets~~capsules/month.	Per FDA labeling
UM ONC_1405	Retevmo (selpercatinib)	Positive change	Remove exclusion criteria: B.Disease progression while receiving Retevmo or another RET inhibitor (e.g., pralsetinib) ~~/MET inhibitor (e.g., vandetinib/cabozantinib).~~	Per Clinical Trial Analysis/Criteria
UM ONC_1419	Danyelza (naxitamab-gqgk)	No Clinical Changes	N/A	N/A
UM ONC_1454	Besremi (ropeginterferon alfa-2b-nijft)	Positive change	Add inclusion criteria: B.Polycythemia Vera 1.Besremi (ropeginterferon alfa-2b-nijft) may be used as monotherapy in members with a confirmed diagnosis of polycythemia vera who have any one of the following: A. Contraindication to hydroxyurea (e.g. childbearing age) B. Intolerance to hydroxyurea C. A lack of therapeutic response to hydroxyurea	Per FDA labeling
UM ONC_1454	Besremi (ropeginterferon alfa-2b-nijft)	Positive change	Remove exclusion criteria: A.Disease progression while taking Besremi (ropeginterferon alfa-2b-nijft) ~~or another Janus kinase (JAK) inhibitor [e.g., Jakafi (ruxolitinib)] .~~ ~~B.Use of Besremi (ropeginterferon alfa-2b-nijft) as initial treatment of Polycythemia Vera.~~ B.C.Concurrent use with other cytoreductive agents (e.g., hydroxyurea), except when transitioning to Besremi (ropeginterferon alfa-2b-nijft).	Per FDA labeling