Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
New	Adstiladrin (nadofaragene firadenovec-vncg)	N/A	N/A	N/A
New	Rezlidhia (olutasidenib)	N/A	N/A	N/A
New	Lunsumio (mosunetuzumab-axgb)	N/A	N/A	N/A
New	Krazati (adagrasib)	N/A	N/A	N/A
UM ONC_1041	LHRH agonists and antagonist	Negative change	Add inclusion criteria: B.Breast Cancer 1.Per NCH policy, the recommended LHRH analogs for the treatment of breast cancer are Trelstar (J3315 triptorelin) and Lupron Depot/Eligard (J9217 leuprolide acetate 7.5 mg or 22.5 mg), 2.NOTE 1: Camcevi SC Depot (J1952 leuprolide mesylate), Firmagon (J9155 degarelix), and Orgovyx (J8999 relugolix) are not indicated for use in breast cancer. 3.NOTE 2: Per NCH Policy, the non-preferred LHRH analogs are Lupron Depot/Lutrate Depot (J1950 leuprolide acetate 3.75 mg or 11.25 mg OR J1954 for Lutrate Depot 22.5 mg) and Zoladex (J9202 goserelin). The above recommendations are based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) showing superior outcomes with one LHRH analog or one dosage form over another in the treatment of breast cancer. An exception would be made if the member is intolerant to, has a contraindication to, or failure on the Preferred LHRH analogs. C.Fertility Preservation in Women Undergoing Cytotoxic Chemotherapy 1.Per NCH policy, the recommended LHRH analogs for the treatment of fertility preservation in women undergoing cytotoxic chemotherapy are Trelstar (J3315 triptorelin) and Lupron Depot/Eligard (J9217 leuprolide acetate 7.5 mg or 22.5 mg), 2.NOTE 1: Camcevi SC Depot (J1952 leuprolide mesylate), Firmagon (J9155 degarelix), and Orgovyx (J8999 relugolix) are not indicated for use in female members who are receiving chemotherapy and desire fertility preservation. 3.NOTE 2: Per NCH Policy, the non-preferred LHRH analogs are Lupron Depot/Lutrate Depot (J1950 leuprolide acetate 3.75 mg or 11.25 mg OR J1954 Lutrate Depot 22.5 mg) and Zoladex (J9202 goserelin). The above recommendations are based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) showing superior outcomes with one LHRH analog over another in the treatment of female members who are receiving chemotherapy and desire fertility preservation, unless the member is intolerant to, has a contraindication to, or failure on the Preferred LHRH analogs. An exception would be made to the above policy if the fertility preservation physician/specialist requests a specific agent and/or a specific dosage form. D.Prostate Cancer 1.Per NCH policy, the recommended LHRH analogs for the treatment of prostate cancer are Trelstar (J3315 triptorelin), Lupron Depot/Eligard (J9217 leuprolide acetate 7.5 mg, 22.5 mg, 30 mg, or 45 mg), and Firmagon (J9155 degarelix). 2.NOTE: Per NCH Policy, the non-preferred LHRH analogs are Lupron Depot/Lutrate Depot (J1950 leuprolide acetate 3.75 mg or 11.25 mg OR J1954 Lutrate Depot 22.5 mg), Camcevi SC Depot (J1952 leuprolide mesylate), Zoladex (J9202 goserelin), and Orgovyx (J8999 relugolix). The above recommendations are based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) showing superior outcomes with one LHRH analog over another in the treatment of prostate cancer, unless the member is intolerant to, has a contraindication to, or failure on the Preferred LHRH analogs.	Per FDA labeling
UM ONC_1041	LHRH agonists and antagonist	Negative change	Add exclusion criteria: A.Zoladex (goserelin), Trelstar (triptorelin), or Lupron Depot/ Lutrate Depot (leuprolide acetate) is being used in postmenopausal female member. B.Zoladex (goserelin), Trelstar (triptorelin), or Lupron/Lutrate (Leuprolide) is being used in member with hormone receptor negative (ER and/or PR negative) breast cancer, except when being used for fertility preservation or for other non-cancer indications. C.Camcevi SC Depot (J1952 leuprolide mesylate), Firmagon (J9155 degarelix), or Orgovyx (J8999 relugolix) is being used in members with breast cancer or for fertility preservation in women undergoing cytotoxic chemotherapy D.Dosing exceeds single dose limit of Lupron Depot/Eligard (leuprolide acetate) IM depot 45 mg every 6 months, Lutrate Depot (leuprolide acetate) 22.5 mg every 3 months, Camcevi SC Depot (leuprolide meseylate) 42 mg every 6 months, Zoladex (goserelin)10.8 mg every 3 months, Trelstar (triptorelin) 22.5 mg every 6 months, Supprelin LA (histrelin) 50 mg every 12 months, Firmagon (degarelix) 240 mg (for loading dose) or 80 mg every month (continuation dose), and Orgovyx (relugolix) 360 mg (for loading dose) or 120 mg (continuation dose).	Per FDA labeling
UM ONC_1063	Oncaspar (pegaspargase)	Positive change	Add inclusion criteria: B.Acute Lymphocytic Leukemia (ALL) including T-Cell Lymphoma/Leukemia ~~1.NOTE: Per NCH Policy & NCH Pathway, Oncaspar (pegasparagase) and Asparlas (calaspargase pegol-mknl) are preferred ove r Erwinaze (erwinia asparaginase) and Rylaze (erwinia asparaginase recombinant) for all subtypes of ALL as a part of anti-leukemia therapy. This recommendation is based on the lack of Level 1 evidence (randomized clinical trials and/or meta-analyses) that shows superior outcomes of Erwinia products over Oncaspar (pegasparagase) and Asparlas (calaspargase pegol-mknl).~~ 1.Oncaspar (pegasparase) ~~use is supported~~ may be used in adults and pediatric members as part of a multi-agent chemotherapy regimen for all sub-types of Acute Lymphocytic Leukemia (ALL), for induction/consolidation therapy, and for therapy of relapsed/refractory disease.	Per NCH Pathway expansion
UM ONC_1063	Oncaspar (pegaspargase)	Negative change	Add exclusion criteria: A.Disease progression on or after an Oncaspar (pegaspargase) containing regimen or following hypersensitivity reactions to another pegylated L-asparaginase [i.e. Asparlas (calaspargase pegol-mknl)].	Per FDA labeling
UM ONC_1132	Rituxan Products	Positive change	Add inclusion criteria: For all indications NOTE 2: Per NCH Policy, Rituxan (rituximab) and Rituxan Hycela (rituximab and hyaluronidase)~~, and Riabni (rituximab-arrx)~~ are non-Preferred drugs. Truxima (rituximab-abbs), Riabni (rituximab-arrx), and Ruxience (rituximab-pvvr) are the Preferred products for the treatment of CD-20 positive NHL and B-ALL. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) demonstrating superiority of one rituximab product over another.	More Cost Effective Alternative(s)
UM ONC_1132	Rituxan Products	Positive change	Remove inclusion criteria: E.Idiopathic Thrombocytopenic Purpura (ITP) 1.The member has acute ITP and Rituximab/rituximab biosimilar is being used as a single agent AND the following: a.The member has ITP that is refractory to corticosteroids ~~and IVIG~~ AND b.The platelet count is less than 30 x 109/L OR c.There are other clinical indications for therapy.	Per Compendia Listing
UM ONC_1204	Caprelsa (vandetarib)	No Clinical Changes	N/A	N/A
UM ONC_1209	Criteria for ~~Preferred~~ Evidence-Based Cancer Therapies	Positive change	Add inclusion criteria: C.The evidence-based cancer therapies may be defined by any of the following criteria: 1.Criteria for Level 1 Pathways: A subset of cancer therapies that have the highest levels of evidence supporting their effectiveness, least toxicity, and all factors being equal, the lowest cost, 2.Criteria for Level 2 Pathways: A subset of cancer therapies that are supported by CMS approved compendia, accepted peer review literature, and/or national clinical practice guidelines (e.g., NCCN, ASCO). 3.Criteria for Low Value Regimens: A subset of cancer therapies characterized by one or more of the following: i.No clinically meaningful survival advantage and/or impaired QOL versus available alternatives. ii.Accelerated approvals using surrogate endpoints and serving no unmet need. iii.Excessive toxicities compared to available alternatives. iv.Excessive cost compared to available alternatives.	Other: Off -label use criteria

UM ONC_1226	Zaltrap (ziv-aflibercept)	No Clinical Changes	N/A	N/A
UM ONC_1232	Stivarga (regorafenib)	Negative change	Add inclusion criteria: C.Gastrointestinal Stromal Tumors (GIST) 1.Stivarga (regorafenib) may be used as a single agent in members with recurrent/inoperable/metastatic GIST who have experienced disease progression on imatinib ~~therapy OR have contraindications/intolerance to imatinib~~ AND sunitinib therapies.	Per FDA labeling
UM ONC_1238	Kadcyla (ado-trastuzumab emtansine)	Positive change	Add inclusion criteria: B.HER-2 Positive Breast Cancer 1. For recurrent/m~~M~~etastatic HER-2 positive breast cancer: Kadcyla (ado-trastuzumab emtansine) may be used as a single agent for members who have experienced disease progression after prior therapy with [trastuzumab + pertuzumab] +/- chemotherapy, e.g., a taxane. 2.For adjuvant therapy of members with stages I-III HER-2 positive breast cancer: Kadcyla (ado-trastuzumab emtansine) can be ~~is the preferred drug~~, used as a single agent in members with stage I-III HER-2 positive breast cancer, who have undergone neoadjuvant chemotherapy (taxane and trastuzumab-based treatment), a nd have residual disease in the breast and/or axillary nodes after surgery.	Per FDA labeling
UM ONC_1261	Cyramza (ramucirumab)	Negative change	Add inclusion criteria: B.Gastric, and Gastroesophageal Junction, and Esophageal Cancers/Colorectal Carcinoma 1.NOTE: Per NCH Policy ~~& NCH Pathway~~, Cyramza (ramucirumab) +/- chemotherapy is a non-Preferred regimen for Gastric, Esophageal, and Gastroesophageal Junction Cancers, and colorectal carcinoma. This recommendation is based on a large meta-analysis of Randomized Clinical Trials (referenced below) which showed increased serious (including fatal) treatment related toxicities with negligible benefits with the use of Cyramza (ramucirumab) in metastatic solid tumors, compared to NCH recommended alternatives agents/regimens, including but not limited to regimens at http://pathways.newcenturyhealth.com. ~~Please refer to the NCH Pathway document for the recommended regimens for the above cancer types.~~ C.Non-Small Cell Lung Cancer (NSCLC) ~~/Colorectal Carcinoma/Hepatocellular Carcinoma~~ ~~1.NOTE: Per NCH Policy & NCH Pathway, Cyramza (ramucirumab) +/- chemotherapy is a non-Preferred regimen for the treatment of all the above cancer types. This recommendation is based on a large meta-analysis of Randomized Clinical Trials (referenced below) which showed increased serious (including fatal) treatment related toxicities with negligible benefits with the use of Cyramza (ramucirumab) in metastatic solid tumors. Please refer to the NCH Pathway document for the recommended/preferred regimens/agents for the above cancer types.~~ 1.NOTE: Per NCH Policy, Cyramza (ramucirumab) + Taxotere (docetaxel)/Tarceva (erlotinib) are non-preferred regimens for the treatment of metastatic NSCLC. This recommendation is based on a large meta-analysis of Randomized Clinical Trials (referenced below) which showed increased serious (including fatal) treatment related toxicities with negligible benefits with the use of Cyramza (ramucirumab) in metastatic solid tumors, compared to NCH recommended alternatives agents/regimens, including but not limited to regimens at http://pathways.newcenturyhealth.com. D.Hepatocellular Carcinoma 1.Cyramza (ramucirumab) may be used as monotherapy for subsequent line treatment of hepatocellular carcinoma in members who have an alpha fetoprotein of ≥400 ng/mL and Child-Pugh Class A only.	Per NCH Pathway exclusion
UM ONC_1263	Keytruda (pembrolizumab)	Negative change	Add inclusion criteria: H.Hepatocellular Carcinoma (HCC) 1.Keytruda (pembrolizumab) will be used in members with hepatocellular carcinoma who have not received prior therapy with an Immune CheckPoint Inhibitor, and have experienced disease progression on or after Nexavar (sorafenib), Lenvima (Lenvatinib), or Stivarga (regorafenib) unless intolerance or contraindications exist to the above 3 agents N.Non-Small Cell Lung Cancer (NSCLC) – Squamous and Non-Squamous 2.NOTE: Per NCH Policy, [Pembrolizumab + Carboplatin + Abraxane (Albumin-bound Paclitaxel)] is a non-preferred regimen for the treatment of NSCLC based on the results of the KEYNOTE- 407 trial which showed equivalent Progression Free Survival and Overall Survival with both Abraxane and Taxol (solvent-based paclitaxel). KEYNOTE-407 is referenced below.~~lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with the above regimen compared to NCH recommended alternatives agents/regimens, including but not limited to regimens at http://pathways.newcenturyhealth.com.~~	Per NCH Pathway exclusion
UM ONC_1263	Keytruda (pembrolizumab)	Positive change	Add inclusion criteria: M.Non-Muscle Invasive Bladder Cancer 1.The member has high risk non-muscle invasive bladder cancer with carcinoma in situ (CIS), with or without papillary tumors, and Keytruda (pembrolizumab) will be used as monotherapy, for intravenous administration, in members who are refractory to local (intravesical) therapy with Bacillus Calmette-Guérin (BCG). Refractory is defined as a loss of response to treatment within 12 months of maintenance therapy with at least the first course of induction (5-6 doses) followed by at least 2 doses of maintenance BCG or the loss of response with the second induction course (of at least 2 doses) of BCG treatment.	Per FDA labeling
UM ONC_1299	Tecentriq (atezolizumab)	Positive change	Add inclusion criteria: B.Alveolar Soft Part Sarcoma (ASPS) 1.Tecentriq (atezolizumab) may be used as monotherapy in adult or pediatric members 2 years of age and older with unresectable or metastatic alveolar soft part sarcoma (ASPS).	New FDA Indication
UM ONC_1299	Tecentriq (atezolizumab)	Negative change	Remove inclusion criteria: ~~B.Breast Cancer~~ ~~1.NOTE: Metastatic Triple Negative Breast Cancer: The combination of Abraxane + Tecentriq (atezolizumab) is NOT recommended per NCH Policy because of the voluntary withdrawal by the manufacturer of Tecentriq (atezolizumab), from the FDA, for the above indication.~~	FDA/NCCN Withdrawal
UM ONC_1299	Tecentriq (atezolizumab)	Negative change	Add inclusion criteria: D.Malignant Melanoma 1.NOTE: The combination of [Cotellic (cobimetinib) + Zelboraf (vemurafenib) + Tecentriq (atezolizumab)] is non-preferred for metastatic malignant melanoma. This position is based on the updated results of the IMspire 150 trial which showed no Overall Survival benefit with the above 3-drug regimen, compared to [Cotellic(cobimetinib) + Zelboraf(vemurafenib)] ~~on the lack of Level 1 evidence (randomized trials and/or meta-analyses) to show superior overall survival outcomes with the above 3-drug combination compared to Cotellic (cobimetinib) + Zelboraf (vemurafenib) regimen.~~ Please see attached reference for the IMspire 150 study.	Per NCH Pathway exclusion
UM ONC_1348	Lumoxiti (moxetumomab pasudotox)	Negative change	Add inclusion criteria: B.Hairy Cell Leukemia ~~1.The member has relapsed/refractory hairy cell leukemia that is positive for CD22 on any standard test AND~~ ~~1.Lumoxiti (moxetumomab pasudotox) will be used as a single agent if the member has experienced disease progression after 2 prior therapies, including a purine analog (e.g. cladribine or pentostatin) AND rituximab.~~ 1.NOTE: Per NCH Policy, Lumoxiti (moxetumomab pasudotox) is not recommended for the treatment of hairy cell leukemia. This recommendation is based on the voluntary withdrawal by the manufacturer of Lumoxiti. Lumoxiti will be discontinued, by August 31, 2023, due to low clinical utilization and the availability of alternative treatment options. Therefore, Lumoxiti's manufacturer advises healthcare providers not to initiate new treatments.	Manufacturer Withdrawal
UM ONC_1352	Asparlas (calaspargase pegol-mknl)	Positive change	Remove inclusion criteria: B.Acute Lymphoblastic Leukemia (ALL) ~~NOTE: Per NCH Policy & NCH Pathway, Asparlas (calaspargase pegol-mknl) and Oncaspar (pegasparagase) are preferred over Erwinaze (erwinia asparaginase) and Rylaze (erwinia asparaginase recombinant) for all subtypes of ALL as a part of anti-leukemia therapy. This recommendation is based on the lack of Level 1 evidence (randomized clinical trials and/or meta-analyses) to show superior outcomes with Erwinia products over Oncaspar (pegasparagase) and Asparlas (calaspargase pegol-mknl).~~	Per NCH Pathway expansion
UM ONC_1352	Asparlas (calaspargase pegol-mknl)	Negative change	Add exclusion criteria: A.Asparlas (calaspargase pegol-mknl) is being used after disease progression with an Asparlas (calaspargase pegol-mknl) containing regimen or following hypersensitivity reactions to another pegylated L-asparaginase [i.e. Oncaspar (pegaspargase)].	Per 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 adult and pediatric members 5 years of age and older with Sickle Cell Disease (e.g., hemoglobin SS, HbS-beta0-thalassemia, and other genotypes of Sickle Cell Disease) and related complications, including pain crisis or acute chest syndrome, within the past 12 months.	Per FDA labeling
UM ONC_1375	Adakveo (crizanlizumab)	No Clinical Changes	N/A	N/A
UM ONC_1393	Sarclisa (isatuximab-irfc)	Positive change	Remove inclusion criteria: B.Multiple Myeloma (MM) 1.Sarclisa (isatuximab-irfc) may be used for members with relapsed or refractory MM ~~who have not received any prior therapy with Darzalex (daratumumab)~~ and any of the following: a.Sarclisa (isatuximab-irfc) is being used in combination with Pomalyst (pomalidomide) and steroid AND the member has failed 2 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).	More Cost Effective Alternative(s)
UM ONC_1393	Sarclisa (isatuximab-irfc)	Negative change	Add exclusion criteria: A.Sarclisa (isatuximab-irfc) is being used on or after disease progression with the same regimen or after disease progression on a daratumumab-based regimen.	Per Compendia Listing
UM ONC_1408	Zepzelca (lurbinectedin)	Negative change	Add inclusion criteria: B.Small Cell Lung Cancer (SCLC) ~~NOTE 1: Zepzelca (lurbinectedin) is a non-preferred agent per NCH Policy and NCH Pathway. Rationale: FDA approval was based on a phase II basket trial. The primary endpoints of the trial were Overall Response Rate and Response Duration. There is no information on disease free survival or overall survival. Please refer to NCH pathway for the preferred subsequent treatments in SCLC.~~ 1.NOTE 1: Per NCH Policy, Zepzelca (lurbinectedin) is a non-preferred agent for the treatment of metastatic/extensive stage Small Cell Lung Cancer (SCLC). This recommendation is based the The FDA approval of Zepzelca was an accelerated approval that was based on a phase II basket trial that used with surrogate endpoints such asof Overall Response Rate and , Response Duration. Furthermore, the ATLANTIS trial (referenced below), a randomized phase III trial, failed to show an Overall Survival benefit for Zepzelca over standard of care 2nd line therapy for extensive stage Small Cell Lung Cancer(iv topotecan or the CAV regimen)., ~~and the lack of data on Overall Survival. Please refer to NCH alternatives agents/regimens recommended by NCH at http://pathways.newcenturyhealth.com.~~ ~~2.NOTE 2: Rate of febrile neutropenia was 5% so primary prophylaxis for febrile neutropenia with a myeloid growth factor (MGF) is not supported/recommended.~~	Per NCH Pathway exclusion
UM ONC_1420	Margenza (margetuximab-cmkb)	Negative change	Add inclusion criteria: B.Metastatic HER-2 + Breast Cancer ~~1.NOTE: Margenza (margetuximab) is a Non-Preferred drug per NCH Pathway and NCH Policy based on a lack of level 1 evidence demonstrating superiority over trastuzumab containing regimens [e.g., trastuzumab +/- chemotherapy, trastuzumab + Perjeta (pertuzumab) +/- chemotherapy, trastuzumab + Tykerb (lapatinib), and Kadcyla (ado-trastuzumab emtansine)]. Please refer to NCH pathway for the preferred treatments in metastatic HER2 positive breast cancer.~~ 1.NOTE: Per NCH Policy, Margenza (margetuximab) + chemotherapy is a non-preferred regimen for the treatment of metastatic HER2 positive breast cancer. This recommendation is based on the Phase 3 SOPHIA trial (please see reference below) which demonstrated no significant Overall Survival benefit over trastuzumab + chemotherapy. Please refer to NCH alternative agents/regimens recommended by NCH, including but not limited to regimens at http://pathways.newcenturyhealth.com.	Per NCH Pathway exclusion
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 mutation confirmed by either tissue biopsy or liquid biopsy (e.g., Guardant 360 or an equivalent FDA approved test), and as initial or subsequent line therapy if was not used previously.~~ ~~2.Members with asymptomatic brain metastases less than 1 cm or less in longest diameter or members with treated brain metastases are also eligible to receive above therapy, provided their disease is positive for a MET exon 14 skipping mutation.~~ NOTE 1: Per NCH Policy, Tepmetko (tepotinib) is a Non- Preferred drug for members with recurrent/metastatic Non-Small Cell Lung Cancer with a positive MET exon 14 skipping mutation (MET + NSCLC). The NCH preferred alternative in the above clinical situation is Trabecta (capamatinib). This position is based on the following: a. Lack of Level 1 evidence (randomized clinical trials and or meta-analyses) to show superior outcomes with Tepmetko over Trabecta. b. Trabecta has a full/regular FDA approval whereas Tepmetko just has an accelerated FDA approval(confirmatory trial data are awaited) NOTE 2: Tepmetko(tepotinib) may be used for members with recurrent/metastatic MET+ NSCLC if there is intolerance/contraindication to the NCH preferred alternative Trabecta(capamatinib)	More Cost Effective Alternative(s)
UM ONC_1043	Tarceva (Erlotinib)	Negative change	Add inclusion criteria: Pancreatic Cancer 1.NOTE: Per NCH Policy, Tarceva (erlotinib) + Gemzar (gemcitabine) is a non-preferred regimen for the treatment of advanced, unresectable, or metastatic pancreatic cancer as initial or subsequent therapy. This recommendation is based on the ~~lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with Tarceva (erlotinib) + Gemzar (gemcitabine) compared to the NCH alternative agents/regimens, including but not limited to regimens at http://pathways.newcenturyhealth.com.~~ LAP07 Clinical Trial which demonstrated no overall survival benefit with Tarceva (erlotinib) + Gemzar (gemcitabine) compared to single agent Gemzar (gemcitabine) for patients with locally advanced pancreatic cancer. Please see reference below.	Per NCH Pathway exclusion
UM ONC_1179	Abraxane (nab-paclitaxel)	Negative change	Add inclusion criteria: E.Melanoma 1.NOTE: Per NCH Policy, Abraxane (albumin-bound paclitaxel) containing regimen is non-preferred as second line or subsequent therapy for the treatment unresectable/metastatic cutaneous melanoma. 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 the NCH recommended alternatives agents/regimens, including but not limited to regimens at http://pathways.newcenturyhealth.com.	Per NCH Pathway exclusion
UM ONC_1201	Yervoy (ipilimumab)	Negative change	Add inclusion criteria: F.Melanoma 1. NOTE: Per NCH policy, Yervoy (ipilimumab) +/- Opdivo (nivolumab) is non-preferred for the adjuvant treatment of resected melanoma. ~~The preferred drugs, per NCH Policies, 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 CheckMate 915 randomized trial data showing inferior outcomes with Yervoy (ipilimumab) + Opdivo (nivolumab) compared to single agent Opdivo (nivolumab) ~~or single agent Keytruda (pembrolizumab)~~, please see reference below. 2.The member has cutaneous melanoma and Yervoy (ipilimumab) may be used as any of the following: a.For unresectable or metastatic melanoma: i.First line therapy in combination with Opdivo (nivolumab) OR ii.Second line or subsequent therapy as a single agent or in combination with Opdivo (nivolumab) in members who have not received prior therapy with Yervoy (ipilimumab). iii.NOTE: Per NCH policy, ~~W~~when Opdivo (nivolumab) is used in combination with Yervoy (ipilimumab), the use of Yervoy (ipilimumab) 3 mg/kg is non-preferred. TThe recommended preferred dose of Yervoy (ipilimumab) should not exceed 1 mg/kg every 3 weeks for a maximum of 4 cycles with Opdivo (nivolumab) dosed at 3 mg/kg (360 mg) every 3 weeks followed by maintenance Opdivo (nivolumab) the latter may be dosed up to 240 mg every 2 weeks, 360 mg every 3 weeks, or 480 mg every 4 weeks. The above recommendation is based on the results of the CheckMate 511 trial which demonstrated a significantly lower incidence of treatment-related adverse events with Ipilimumab 1 mg/kg compared to 3 mg/kg, when used in combination with Opdivo (nivolumab) in patients with advanced or metastatic melanoma.	Per NCH Pathway exclusion

UM ONC_1249	Mekinist (trametinib)	Positive change	Remove inclusion criteria: B.Malignant Melanoma 1.Mekinist (trametinib) may be used as adjuvant treatment, following complete resection, in combination with Tafinlar (dabrafenib) for melanoma with BRAF V600E or V600K mutations. ~~a.NOTE: For adjuvant therapy of BRAF V600 E or V600K mutation positive, stage III melanoma, the preferred agents per NCH Policies & NCH Pathway are Opdivo (nivolumab) OR Keytruda (pembrolizumab). Tafinlar (dabrafenib) + Mekinist (trametinib) is non-preferred for use in the adjuvant setting based on a lack of Level 1 evidence that nivolumab or pembrolizumab monotherapy is inferior to the above combination. Please refer to UM ONC_1274 Opdivo (nivolumab) or UM ONC_1263 Keytruda (pembrolizumab) policy.~~ 2.Mekinist (trametinib) may be used in combination with Tafinlar (dabrafenib) in members with unresectable or metastatic BRAF V600E or V600K mutation positive melanoma and who have intolerance to/contraindication to the use of the preferred MEK and BRAF inhibitor combination, Cotellic (cobimetinib) + Zelbroaf (vemurafenib). ~~a.NOTE: For systemic therapy of metastatic BRAF V600E or V600K mutation positive melanoma the preferred oral combination, per NCH Policies and NCH Pathway, is Cotellic (cobimetinib) + Zelboraf (vemurafenib). This recommendation is based on a lack of Level 1 evidence to show superiority of one combination of BRAF and MEK inhibitor over another. Please refer to UM ONC_1279 Cotellic (cobimetinib) or UM ONC_1207 Zelboraf (vemurafenib) policy.~~	Per NCH Pathway expansion
UM ONC_1250	Tafinlar (dabrafenib)	Positive change	Remove inclusion criteria: B.BRAF V600E or V600K mutation positive Melanoma 1.Tafinlar (dabrafenib) may be used in combination with Mekinist (trametinib) as adjuvant treatment, following complete resection, for melanoma with BRAF V600E or V600K mutations. ~~a.NOTE: For adjuvant therapy of BRAF V600 E or V600K mutation positive, stage III melanoma, the preferred agents per NCH Policies & NCH Pathway are Opdivo (nivolumab) OR Keytruda (pembrolizumab). Tafinlar (dabrafenib) + Mekinist (trametinib) is non-preferred for use in the adjuvant setting based on a lack of Level 1 evidence that nivolumab or pembrolizumab monotherapy is inferior to the above combination. Please refer to UM ONC_1274 Opdivo (nivolumab) or UM ONC_1263 Keytruda (pembrolizumab) policy.~~ 2.Tafinlar (dabrafenib) may be used as a single agent or in combination with Mekinist (trametinib) in members with unresectable or metastatic BRAF V600E or V600K mutation positive melanoma and who have intolerance to/contraindication to the use of the preferred MEK and BRAF inhibitor combination, Cotellic (cobimetinib) + Zelboraf vemurafenib). ~~a.NOTE: For systemic therapy of metastatic BRAF V600E or V600K mutation positive melanoma the preferred oral combination, per NCH Policies and NCH Pathway, is cobimetinib + vemurafenib. This recommendation is based on a lack of Level 1 evidence to show superiority of one combination of BRAF and MEK inhibitor over another. Please refer to UM ONC_1279 Cotellic (cobimetinib) or UM ONC_1207 Zelboraf (vemurafenib) policy.~~	Per NCH Pathway expansion
UM ONC_1274	Opdivo (nivolumab)	Negative change	Add inclusion criteria: I.Melanoma ~~1.Opdivo (nivolumab) may be used in members with stage III or metastatic/recurrent melanoma as follows:~~ ~~a.As a single agent for adjuvant therapy of high-risk Stage III melanoma following complete resection of the primary tumor with or without a complete regional lymph node dissection. Maximum duration of therapy is one year.~~ NOTE: Adjuvant Yervoy (ipilimumab) +/- Opdivo (nivolumab) is ~~not recommended~~ non-preferred in this setting for the adjuvant treatment of high risk resected melanoma. This recommendation is based on CheckMate 915 randomized trial data showing inferior outcomes with Yervoy (ipilimumab + Opdivo (nivolumab) compared to single agent Opdivo (nivolumab), please see reference below. b.As a single agent or in combination with Yervoy (ipilimumab) for recurrent/metastatic melanoma as initial therapy or as subsequent therapy (if the combination was not used previously). 2.NOTE: Per NCH policy, w~~W~~hen Opdivo (nivolumab) is used in combination with Yervoy (ipilimumab), the use of Yervoy (ipilimumab) 3 mg/kg is non-preferred. The ~~recommended~~ preferred dose of Yervoy (ipilimumab) should not exceed 1 mg/kg every 3 weeks for a maximum of 4 cycles with Opdivo (nivolumab) dosed at 3 mg/kg (up to 360 mg) every 3 weeks followed by maintenance Opdivo (nivolumab) 240 mg every 2 weeks, 360 mg every 3 weeks, or 480 mg every 4 weeks. The above recommendation is based on the results of the CheckMate 511 trial which demonstrated a significantly lower incidence of treatment-related adverse events with Ipilimumab 1 mg/kg compared to 3 mg/kg, when used in combination with Opdivo (nivolumab) in patients with advanced or metastatic melanoma.	Per NCH Pathway exclusion
UM ONC_1290	Yondelis (trabectedin)	Negative change	Add inclusion criteria: B.Soft Tissue Sarcoma 1.The member has unresectable or metastatic soft tissue sarcoma (Leiomyosarcoma, liposarcoma, and translocation-related sarcomas) AND Yondelis (trabectedin) will be used as monotherapy following disease progression with an anthracycline-based chemotherapy, unless there is a contraindication/intolerance with prior anthracycline based therapy. 2.NOTE: Per NCH Policy, the use of Yondelis (trabectedin) is non-preferred for the treatment for other soft tissue sarcoma histologies that are not leiomyosarcoma, liposarcoma, and translocation-related sarcomas. ~~This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with compared to alternative agents/regimens recommended by NCH (http://pathways.newcenturyhealth.com).~~ This recommendation is based on the T-SAR trial which demonstrated no clinically meaningful improvement in overall survival or progression free survival with Yondelis (trabectedin) when compared to best supportive care for patients with advanced translocation-related sarcoma. Please see reference below.	Per NCH Pathway exclusion
UM ONC_1401	Tukysa (tucatinib)	Positive change	Add inclusion criteria: B.Breast Carcinoma 1.Tukysa (tucatinib) may be used in members with metastatic HER-2 positive breast cancer who have experienced disease progression on ~~two~~ one or more anti HER-2 regimens including a regimen containing [pertuzumab and trastuzumab] AND/OR either Kadcyla (ado-trastuzumab emtansine) or Enhertu (fam-trastuzumab deruxtecan).	Per FDA labeling
UM ONC_1429	Abecma (idecabtagene vicleucel)	Negative change	Add inclusion criteria: B.Multiple Myeloma 1.Abecma (idecabtagene vicleucel) may be used for adult members with relapsed/refractory multiple myeloma that have progressed on 4 or more lines of therapy AND 2.Members must have triple refractory disease as defined in the KaMMa trial: refractory to an immunomodulatory agent (e.g., lenalidomide, thalidomide, pomalidomide), a proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib), and an anti-CD38 antibody (e.g., daratumumab, isatuximab) AND. 3.Members must have measurable disease or evidence of disease progression from the last line of therapy for multiple myeloma.	Per Clinical Trial Analysis/Criteria
UM ONC_1460	Carvykti (ciltacabtagene autoleucel)	Negative change	Add inclusion criteria: B.Multiple Myeloma 1.Carvykti (ciltacabtagene autoleucel) may be used for adult members with relapsed/refractory multiple myeloma that have progressed on 4 or more lines of therapy AND 2.Members must have triple class refractory disease defined as: refractory to an immunomodulatory agent (e.g., lenalidomide, thalidomide, pomalidomide), a proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib), and an anti-CD38 antibody (e.g., daratumumab, isatuximab) AND 3.Members must have measurable disease or evidence of disease progression from the last line of therapy for multiple myeloma.	Per Clinical Trial Analysis/Criteria
UM ONC_1462	Opdualag (nivolumab and relatlimab-rmbw)	Positive change	Remove inclusion criteria: B.Melanoma 1.Opdualag (nivolumab and relatlimab-rmbw) may be used as a fixed dose combination, as first line therapy, in adult or in pediatric members 12 years of age or older who weigh at least 40 kg (88 pounds) with unresectable or metastatic (Stage III-IV) cutaneous melanoma, regardless of BRAF mutation status. ~~2.NOTE: Per NCH Pathway & NCH Policy, Opdualag (nivolumab and relatlimab-rmbw) is a non-Preferred drug for the treatment of cutaneous melanoma. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with Opdualag compared to combination therapy with Opdivo (nivolumab) + Yervoy (ipilimumab).~~	Per NCH Pathway expansion