Policy	Drug(s)	Type of Change	Brief Description of Policy Change
UM ONC_1179	Abraxane (nab-paclitaxel)	Negative change	Add inclusion criteria: NCH Policy & NCH Pathway prefers/recommends the use of solvent-based paclitaxel (Taxol) or docetaxel (Taxotere) over the use of Abraxane. (Taxotere was added)
UM ONC_1179	Abraxane (nab-paclitaxel)	Positive change	Add inclusion criteria: 2.Breast Cancer a.For recurrent/metastatic triple negative breast cancer that is PD-L1 positive and Abraxane (nab-paclitaxel) is being used in combination with atezolizumab
UM ONC_1179	Abraxane (nab-paclitaxel)	Negative change	Remove inclusion criteria: Breast Cancer 1. The member has breast cancer and Abraxane (nab-paclitaxel) is being used as a single agent or in combination with carboplatin for members with recurrent or metastatic human epidermal growth factor receptor 2-negative disease 2. In combination with trastuzumab for recurrent or metastatic human epidermal growth factor receptor 2-positive disease.

UM ONC_1179	Abraxane (nab-paclitaxel)	Negative change	Remove inclusion criteria: Non-Small Cell Lung Cancer (NSCLC) a. The member has recurrent or metastatic NSCLC and Abraxane (nab-paclitaxel) is being used as ONE of the following: i. As first line therapy: As a single agent for members with EGFR, ALK, ROS1, BRAF and PD-L1 <50% negative or unknown OR ii. As first line therapy: For use in combination with carboplatin + pembrolizumab (squamous cell histology) or carboplatin + atezolizumab (non-squamous cell histology) for EGFR, ALK, ROS1negative or unknown. NOTE: In this setting NCH Policy recommends the use of solvent based paclitaxel (Taxol) because peer reviewed literature showed the both Abraxane and Taxol to be equally effective OR iii. As subsequent therapy: For use as a single agent or in combination with platinum-based regimens following prior erlotinib, afatinib, gefitinib, dacomitinib, osimertnib, ceritinib, alectinib, brigatinib, or crizotinib (for EGFR mutation or ALK/ROS-1-positive tumors).
UM ONC_1179	Abraxane (nab-paclitaxel)	Negative change	Add inclusion criteria: NOTES: Per NCH Policy & NCH Pathway recommends the use of solvent based paclitaxel (Taxol) is preferred over Abraxane for NSCLC. Please refer to NCH Pathway for the recommended regimens/agents for Non Small Cell Lung Cancer
UM ONC_1179	Abraxane (nab-paclitaxel)	Negative change	Add inclusion criteria: Pancreatic Adenocarcinoma b. Used in combination with gemcitabine for first or subsequent line therapy for recurrent/metastatic disease (for patients who have not received the above regimen for metastatic disease)
UM ONC_1179	Abraxane (nab-paclitaxel)	Positive change	Remove exclusion criteria: 1. Abraxane (nab-paclitaxel) is being used in the adjuvant treatment of breast, pancreatic, or NSCLC.

UM ONC_1203	Adcetris (brentiximab)	Negative change	Add inclusion criteria: Classical Hodgkin Lymphoma NOTE: The preferred regimen for first line therapy in stage III and IV and high risk stage I and II disease, per NCH Policies and NCH Pathways, is ABVD (doxorubicin, bleomycin, vinblastine, dacarbazine) + rituximab for primary treatment of Hodgkin lymphoma- except in members with contraindications or intolerance to Bleomycin (e.g. lung disease). v. Weight calculation, for dosage, not to exceed 100kg which translates to no more than 180mg per dose (as monotherapy) or 120 mg per dose (in combination with chemotherapy).
UM ONC_1203	Adcetris (brentiximab)	Positive change	Remove inclusion criteria: Non Hodgkin Lymphoma ii.Weight calculation, for dosage, not to exceed 100kg which translates to no more than 180mg per dose.
UM ONC_1203	Adcetris (brentiximab)	Positive change	Add inclusion criteria: Peripheral T-Cell Lymphomas (PTCL) as a single agent or combination with chemotherapy all line of therapies
UM ONC_1203	Adcetris (brentiximab)	Negative change	Add inclusion criteria: Breast Implant Associated Anaplastic Lymphoma - Disease is documented to be CD-30 positive
UM ONC_1203	Adcetris (brentiximab)	Positive change	Remove exclusion criteria: 2.Avoid use in severe renal impairment (creatinine clearance less than 30 mL/min) or moderate to severe hepatic impairment (Child-Pugh B or C).
UM ONC_1203	Adcetris (brentiximab)	Negative change	Add exclusion criteria: 4.Treatment with Adcetris (brentuximab vedotin) exceeds the maximum duration limit of 16 cycles as a part of AAVD(12 doses for first line treatment of Hodgkin's Disease), OR exceeds); 16 cycles for refractory/relapsed disease/ or consolidation treatment after HSCT of HD; OR exceedsor 8 doses for previously untreated PTCL .

UM ONC_1306	Bavencio (avelumab)	Negative change	Add inclusion criteria: 3. Urothelial Carcinoma including carcinomas of the upper Genito-Urinary Tract & Urethra(UC)- NOTES: NCH L1 Pathway Preferred Drug: Keytruda (pembrolizumab) is the preferred agent over other PD-1 or PD-L1 inhibitors (i.e. Opdivo, Tecentriq, Bavencio, Imfinzi), for second line following platinum containing therapy, regardless of the PD-L1 status..4.Renal Cell Carcinoma (RCC)- NCH L1 Pathway Preferred Drug: Opdivo (nivolumab)- given as a single agent or incombination 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] i.e. Tecentriq, Bavencio, Imfinzi, Keytruda), for initial therapy for metastatic renal cell carcinoma
UM ONC_1306	Bavencio (avelumab)	Positive change	Remove exclusion criteria: 2. Concurrent use with other anticancer treatments, steroids, or immunosuppressive agents.
UM ONC_1260	Beleodaq (belinosat)	Positive change	Remove inclusion criteria: Has a failure, contraindications, or intolerance to at least one prior therapy including CHOP or platinum containing regimens (i.e. ICE, DHAP, ESHAP, GDP, or GemOx)
UM ONC_1260	Beleodaq (belinosat)	Negative change	Add exclusion criteria: 1. Off-label indications for Beleodaq (belinosat) in primary cutaneous lymphomas shall be reviewed for appropriateness per National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or other compelling medical literature publications.
UM ONC_1330	Besponsa (inotuzumab ozogamicin)	Positive change	Remove inclusion criteria: 1.Acute Lymphoblastic Leukemia (ALL)- remove failure to standard chemotherapy if philadelphia chromosome positive; ecog 0-2
UM ONC_1330	Besponsa (inotuzumab ozogamicin)	Positive change	Remove exclusion criteria: 2. Concurrent use with monoclonal antibodies or chemotherapy. 3.Total bilirubin >1.5 x upper limit of normal (ULN) and AST and ALT >2.5 x ULN.
UM ONC_1270	Blincyto (blinatumomab)	Positive Change	Add inclusion criteria: 1. Acute Lymphoblastic Leukemia (ALL)- NOTE: NCH Pathway Preferred Regimen for relapsed/refractory CD19 positive B-cell ALL is Blinatumomab over chemotherapy.

UM ONC_1270	Blincyto (blinatumomab)	Negative change	Add inclusion criteria: 1. Acute Lymphoblastic Leukemia (ALL)- CD 19 positive B cell ALL
UM ONC_1270	Blincyto (blinatumomab)	Positive change	Remove exclusion criteria: 2.Concurrent use with other chemotherapy, immunotherapy, or tyrosine kinase inhibitors (i.e. imatinib, nilotinib, or dasatinib)
UM ONC_1190	Bone Modifying Agents (Aredia, Zometa, Xgeva/Prolia)	Negative change	Add inclusion criteria: NOTE: The preferred agent, per NCH Policies & NCH Pathway, is IV bisphosphonate (Zometa/Reclast or Aredia) over Xgeva/Prolia (denosumab) for bone metastases from solid tumors, for prevention/treatment of osteoporosis/bone loss, and as adjuvant therapy to decrease the risk of bone metastases in ER/PR+ breast cancer. Xgeva is an acceptable alternative and is preferred for members with documented renal impairment and a CrCl of < 30 mL/min. 2. MM- b.NOTE: For use of Xgeva (denosumab) may be used for the above indication if, the member has failed, is intolerant to, or has a contraindication to IV bisphosphonates (zoledronic acid or pamidronate).
UM ONC_1190	Bone Modifying Agents (Aredia, Zometa, Xgeva/Prolia)	Positive change	Remove inclusion criteria: 2. MM- c.Bone disease is evident on plain radiographs or imaging studies OR d.Osteopenia is evident on bone mineral density studies OR e.If negative for bone disease, the member is currently receiving therapy for multiple myeloma and/or up to 2 years beyond active treatment.
UM ONC_1190	Bone Modifying Agents (Aredia, Zometa, Xgeva/Prolia)	Negative change	Add inclusion criteria: DOSE ADJUSTMENTS FOR ZOLEDRONIC ACID FOR USE IN MYELOMA & SKELETAL METASTASES: <30- Use is not recommended
UM ONC_1190	Bone Modifying Agents (Aredia, Zometa, Xgeva/Prolia)	Negative change	Add inclusion criteria: a The member has prostate cancer and Zoledronic acid is used for prevention or treatment of osteoporosis during androgen deprivation therapy for members who are 70 years or higher or are at high risk for fractures

UM ONC_1190	Bone Modifying Agents (Aredia, Zometa, Xgeva/Prolia)	Positive change	Remove exclusion criteria: 1. IV Bisphosphanates (Aredia or Zometa) is being used in members with any of the following: a. Solitary plasmacytomas or smoldering or indolent myeloma without documented lytic bone disease b. Monoclonal gammopathy of undetermined significance c. Postmenopausal females or glucocorticoid therapy-induced osteoporosis d. Mild or asymptomatic hypercalcemia or hypercalcemia not related to cancer e. Lytic bone disease not evident on plain radiographs or imaging studies f. Osteopenia or osteoporosis not evident on bone mineral density studies g. Concomitant use with Reclast or other bisphosphanates (oral or IV) 2. Member with hypocalcemia or has a pre-existing disturbance of mineral metabolism (e.g., hypoparathyroidism, thyroid or parathyroid surgery, vitamin D deficiency, malabsorption syndromes, excision of small intestine) that has not been effectively corrected or treated. 3. Member has had a recent dental procedure such as a tooth extraction that increases the risk for osteonecrosis of the jaw. 4. In hypercalcemia of malignancy, retreatment doses is less than 7 days apart. 5. Treatment with Bone Modifying agents exceeds the maximum 24 months duration limit.
UM ONC_1190	Bone Modifying Agents (Aredia, Zometa, Xgeva/Prolia)	Negative change	Add exclusion criteria: a. Members with creatinine clearance < 60 mL/min without Zometa dose adjustment,

UM ONC_1237	Cometriq/Cabometyx (cabozantinib)	Negative change	Add inclusion criteria: 2.Kidney Cancer- a. NOTE: The preferred tyrosine kinase inhibitor, per NCH Policy & NCH Pathwayies, for advanced/metastatic RCC is CABOMETYX (cabozantinib) in the first line setting for Intermediate/Poor Risk disease, and for subsequent therapy for any risk disease; add IMDC criteria b.CABOMETYX (cabozantinib) may be used in metastatic/inoperable renal cell carcinoma in the first line setting for Intermediate/Poor Risk disease (IMDC Criteria) OR Subsequent line therapy regardless of IMDC Risk
UM ONC_1237	Cometriq/Cabometyx (cabozantinib)	Negative change	Add inclusion criteria: 4. Hepatocellular Carcinoma- NOTE: The preferred tyrosine kinase inhibitor, per NCH Policy & NCH Pathwyaies, for subsequent line therapy of unresectable or metastatic HCC is REGORAFENIB
UM ONC_1237	Cometriq/Cabometyx (cabozantinib)	Negative change	Add exclusion criteria: 1. Off-label indications for CABOMETYX (cabozantinib) in non-small cell lung cancer shall be reviewed for appropriateness per National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or other compelling medical literature publications.
UM ONC_1237	Cometriq/Cabometyx (cabozantinib)	Positive change	Remove exclusion criteria: 1. The member has indolent or slowly progressing thyroid disease. 4. Prior treatment with Afinitor (everolimus) or Torisel (temsirolimus). 5. Concurrent use with other tyrosine kinase inhibitors.
UM ONC_1261	Cyramza (ramucirumab)	Negative change	Add inclusion criteria: 1. Gastric and Gastroesophageal Junction Cancers - The preferred agents/regimens, per NCH Policies & NCH Pathway, for subsequent therapy of advanced/metastatic gastric or gastroespophageal junction adenocarcinoma are single agents including paclitaxel, docetaxel, or irinotecan. Please refer to the NCH Pathway document for recommended regimens for the above cancer types
UM ONC_1261	Cyramza (ramucirumab)	Negative change	Remove inclusion criteria: 3. Non-Small Cell Lung Cancer (NSCLC)/ Colorectal Carcinoma/Hepatocellular Carcinoma - Please refer to the NCH Pathway document for recommended regimens for the above cancer types

UM ONC_1261	Cyramza (ramucirumab)	Positive change	Remove exclusion criteria: 1. Cyramza (ramucirumab) is being used in members with a history of severe bleeding, blood clots, symptomatic heart disease, uncontrolled high blood pressure, stroke, active infection, kidney disease, or recent surgery.
UM ONC_1235	Doxil (liposomal doxorubicin)	Negative change	Add inclusion criteria: f. NOTE: The preferred agent, per NCH Policies, is standard Doxorubicin (Adriamycin) when used for for Hodgkin lymphoma and breast cancer.
UM ONC_1235	Doxil (liposomal doxorubicin)	Negative change	Add inclusion criteria: 3. Multiple Myeloma- 2. NOTE: Please refer to NCH Pathway for L1 preferred regimens/agents for initial and subsequent therapy for relapsed/refractory Multiple Myeloma
UM ONC_1235	Doxil (liposomal doxorubicin)	Negative change	Remove inclusion criteria: MM - For the treatment of relapsed or refractory multiple myeloma and Doxil/Lipodox (liposomal doxorubicin) is being used in combination with bortezomib in memberspatients who have received at least 1 prior therapy and is bortezomib naive.
UM ONC_1235	Doxil (liposomal doxorubicin)	Negative change	Remove inclusion criteria: 3. Ovarian cancer- After platinum-based chemotherapy in combination with bevacizumab if bevacizumab not previously received .
UM ONC_1235	Doxil (liposomal doxorubicin)	Negative change	Remove inclusion criteria: B-Cell Lymphomas, breast cancer, Hodgkin lymphoma, soft tissue sarcoma, uterine cancers, primary cutaneous lymphoma, and T-cell lymphoma, all criteria.
UM ONC_1235	Doxil (liposomal doxorubicin)	Positive change	Remove exclusion criteria: 2. History of severe hypersensitivity reactions, including anaphylaxis, to standard doxorubicin (Adriamycin). 3. Concurrent use with another anthracycline. 6. Members who have not progress after initial treatment of their KS, multiple myeloma or ovarian cancer.
UM ONC_1039	Faslodex (Fulvestrant)	Negative change	Add inclusion criteria: 2. Metastatic Breast Cancer ER/PR positive- NOTE: NCH Pathway L1 Preferred Regimens for ER/PR positive metastatic breast cancer, for first line/initial therapy are [Ribociclib/Palbociclib + Aromatase Inhibitor]. Abemaciclib +/- Fulvestrant is preferred in the subsequent or second line setting.

UM ONC_1039	Faslodex (Fulvestrant)	Negative change	Add exclusion criteria: 1. Requests for Faslodex for use in ovarian and uterine neoplasms will be reviewed on a cas-by-case basis using NCCN and other compendia, and peer reviewed literature.
UM ONC_1308	Folotyn (pralatrexate)	Negative change	Add exclusion criteria: 1. Off-label indications for Folotyn (pralatrexate) in Primary Cutaneous Lymphomas shall be reviewed for appropriateness per National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or other compelling medical literature publications. 2. Concurrent use with other anti-cancer therapy.
UM ONC_1259	Gazyva (obinutuzumab)	Negative change	Add inclusion criteria: 2. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)/ Follicular Lymphoma- NOTE: The preferred agents for requests for Rituxan and Gazyva, per NCH Policy & NCH Pathway,are Truxima & Ruxience. Please refer to the NCH Pathway document for recommended regimens for initial and subsequent therapy for the above neoplasms
UM ONC_1259	Gazyva (obinutuzumab)	Positive change	Remove exclusion criteria: 1.The member has an active infection requiring systemic treatment.
UM ONC_1258	Gilotrif (afatinib)	Negative change	Add inclusion criteria: NSCLC - NOTE: The preferred agent, per NCH Policy & NCH PathwayPathways and per NCH policies, for first line therapy of recurrent/metastatic, EGFR mutation positive Non Small Cell Lung Cancer is Osimertinib. Gilotrif (afatinib) may be used when tThe member has recurrent, or metastatic EGFR mutation positive NSCLC and Gilotrif (afatinib) is being used as a single agent in any of the following clinical situations:For subsequent therapy upon disease progression on another first line TKI agenttherapy (e.g. Osimertinib), and the members's cancer is negative for the T790M mutation.
UM ONC_1258	Gilotrif (afatinib)	Negative change	Add exclusion criteria: 1. Gilotrif use in a patient with metastatic Non Small Cell Lung Cancer that is positive for the T790M mutation. 2. Concurrent use with other anti-cancer therapy.

UM ONC_ 1177	Gleevec (imatinib)	Negative change	Add inclusion criteria: 1. Chronic myeloid leukemia (CML)- NOTE: In the absence of a resistant mutation (i.e. a mutation the confers resistance to imatinib)al status, the preferred agent for initial and subsequent line of therapy is IMATINIB.
UM ONC_ 1177	Gleevec (imatinib)	Negative change	Add inclusion criteria: 2 Acute lymphoblastic leukemia (ALL)- NOTE: Per NCH Policy & NCH Pathway If Ph or BCR-ABL positive, the preferred tyrosine kinase inhibitor for this disease, is IMATINIB, unless the member is intolerant to/has disease that is refractory to Imatinib.
UM ONC_ 1177	Gleevec (imatinib)	Negative change	Remove inclusion criteria: 4.NHL - Lymphoblastic Lymphoma -Induction or reinduction therapy for Philadelphia chromosome-positive stage I-IV disease as a component of HyperCVAD (cyclophosphamide, vincristine, doxorubicin, and dexamethasone alternating with high-dose methotrexate and cytarabine) regimen with rituximab in CD20-positive disease.
UM ONC_ 1177	Gleevec (imatinib)	Positive change	Remove inclusion criteria: Melanoma - ecog performance status 0-2
UM ONC_ 1177	Gleevec (imatinib)	Negative change	Add inclusion criteria: 7. Gastrointestinal stromal tumors (GIST)- NOTE: The preferred agent, per NCH Pathway & NCH Policies, for primary or initial therapy is IMATINIB.
UM ONC_ 1177	Gleevec (imatinib)	Negative change	Add inclusion criteria: 1. The member has a diagnosis of HES or CEL with a positive test for FIPL1L-PDGFR alpha fusion kinase; 2. The member has aggressive SM without D816V c-Kit mutation or if eosinophilia is present with FIP1L1-PDGFRA fusion gene

UM ONC_ 1177	Gleevec (imatinib)	Positive change	Remove exclusion criteria: 1. Gleevec (imatinib mesylate) is being used in members with Philadelphia chromosome or BCR-ABL negative CML. 2. Gleevec (imatinib mesylate) is being used in members with DFSP negative for t(17;22) translocation. 3. Gleevec (imatinib mesylate) is being used in members with CD117 (Kit) negative GIST. 4. Gleevec (imatinib mesylate) is being used in members with refractory or relapse disease positive for BCR-ABL or c-kit mutations AND/OR disease progression on high dose Gleevec (imatinib mesylate). 5. Use of high dose without a failure to low dose Gleevec (imatinib mesylate). 6.1. Disease progression on Gleevec (imatinib)Dosing exceeds single dose limit of Gleevec (imatinib mesylate) 800 mg.
UM ONC_ 1177	Gleevec (imatinib)	Negative change	Add exclusion criteria: 6. Disease progression on Gleevec (imatinib): Dosing exceeds single dose limit of Gleevec (imatinib mesylate) 800 mg.

UM ONC_1134	Herceptin/Ogivri/Herzuma/Ontruzant/Kanjinti/Trazimera (trastuzumab/trastuzumab-dkst/trastuzumab-pkrb/trastuzumab-dttb/trastuzumab-anns/trastuzumab-qyyp)	Positive change	Add inclusion criteria: 2. HER-2 Positive Breast Cancer- i. In combination with chemotherapy and/or Pertuzumab for neoadjuvant or adjuvant therapy. NOTE: A. Pertuzumab + Trastuzumab is indicated only in patients with a tumor size 2 cm or higher, node positive disease or ER/PR negative disease. The combination may be used in the neoadjuvant setting. In the adjuvant setting it may be used if : a. No neoadjuvant therapy was given, OR b. Neoadjuvant therapy was given and there was no residual disease found in the breast/axillary nodes at surgery. NOTE:B. If neoadjuvant therapy was given and if there is evidence of residual disease in the breast and or axillary nodes, then the Preferred drug per NCH Policy & NCH Pathway is Kadcyla. ii. First line or subsequent line therapy for recurrent or metastatic disease setting: 1. In combination with tamoxifen, fulvestrant, or an aromatase inhibitor for a member whose disease is also ER/PR positive. OR 2. In combination with pertuzumab and a taxane (docetaxel or paclitaxel) regardless of the ER/PR status
UM ONC_1134	Herceptin/Ogivri/Herzuma/Ontruzant/Kanjinti/Trazimera (trastuzumab/trastuzumab-dkst/trastuzumab-pkrb/trastuzumab-dttb/trastuzumab-anns/trastuzumab-qyyp)	Positive change	Add inclusion criteria: 3. Gastric/Esophageal and Esophagogastric Junction Cancers- Herceptin/Ogivri/Herzuma/Ontruzant/Kanjinti/Trazimera is being used in combination with oxaliplatin and 5-fluorouracil (or capecitabine) as first line therapy
UM ONC_1366	Inrebic (fedratinib)	Positive change	Remove inclusion criteria: 1.2. Myelofibrosis (MF)- d. The member has failed prior therapy with hydroxyurea, busulfan, 2-chlorodeoxyadenosine, erythropoiesis-stimulating agents, androgens, immunomodulators (thalidomide, lenalidomide) or interferon AND f. A baseline platelet count 50 x 109 cells/L or greater.

UM ONC_1366	Inrebic (fedratinib)	Positive change	Remove exclusion criteria: 1.Inrebic (fedratinib) is being used after disease progression with prior treatment with a Janus Kinase 2 (JAK2) inhibitor. 3.The member has any of the following: a.Splenectomy b.Known active (acute or chronic) Hepatitis A, B, or C infection c.AST or ALT ≥ 2.5 x ULN or Total Bilirubin ≥ 3.0 x ULN d.Prior history of chronic liver disease (e.g., chronic alcoholic liver disease, autoimmune hepatitis, sclerosing cholangitis, primary biliary cirrhosis, hemochromatosis, non-alcoholic steatohepatitis
UM ONC_1309	Iressa (gefitinib)	Negative change	Add inclusion criteria: 1.Non-Small Cell Lung Cancer (NSCLC)- NOTE: The preferred agent, per NCH policies & NCH Pathway, for first line therapy of recurrent/metastatic, EGFR mutation positive Non Small Cell Lung Cancer ,is Osimertinib. b. Iressa (gefitinib) is being used as a single agent in members with a known EGFR sensitizing mutation as subsequent line therapy; may be used as first line therapy in a memberpatient who has a contraindication/intolerance to Osimertinib.
UM ONC_1309	Iressa (gefitinib)	Positive change	Remove exclusion criteria: 3.Dosing exceeds single dose limit of Iressa (gefitinib) 250 mg or 500 mg (with concomitant strong CYP450 3A4 enzyme inducers).
New	Jadenu (deferasirox)	n/a	n/a
UM ONC_1242	Jakafi (ruxolitinib)	Negative change	Add inclusion criteria: 1. Myelofibrosis- NOTE: The preferred agent, per NCH Policies, is Jakafi (ruxolitinib) for all of the following indications,
UM ONC_1242	Jakafi (ruxolitinib)	Positive change	Remove inclusion criteria: 1. Myelofibrosisd-The member has failed prior therapy with hydroxyurea, busulfan, 2- chlorodeoxyadenosine, erythropoiesis-stimulating agents, androgens, immunomodulators (thalidomide, lenalidomide) or interferon.

UM ONC_1238	Kadcyla (ado-trastuzumab emtansine)	Negative change	Add inclusion criteria: 1.HER-2 positive Breast Cancer - a. For Metastatic HER-2 positve Breast cancer: Kadcyla (ado-trastuzumab emtansine) is being used as a single agent in members with metastatic HER-2 positive breast cancer who have experienced disease progression after first line therapy with a taxane + trastuzumab + Pertuzumab .
UM ONC_1310	Kisqali (ribociclib)	Negative change	Add inclusion criteria: NOTE: The preferred CDK4/6 inhibitors, per NCH Pathway & NCH Policies, for first and subsequent line of therapy of recurrent or metastatic hormone receptor positive and HER-2 negative breast cancer are Ribociclib and Palbociclib.
UM ONC_1310	Kisqali (ribociclib)	Positive change	Add inclusion criteria: a. The member has recurrent or metastatic breast cancer and Kisqali (ribociclib) is being used in combination with fulvestrant ii. Member is postmenopausal OR if member is premenopausal she is also receiving ovarian suppression, e.g. with leuprolide
UM ONC_1224	Kyprolis (carfilzomib)	Negative change	Add inclusion criteria: MM a. Initial Therapy- Please refer to the NCH Pathway document for preferred/Level 1 recommended therapies for the initial treatment of Multiple Myeloma
UM ONC_1224	Kyprolis (carfilzomib)	Negative change	Remove inclusion criteria: Multiple Myeloma- In combination with lenalidomide/cyclophosphamide and dexamethasone as primary chemotherapy For relapsed/refractory disease: 1. In combination with dexamethasone + daratumumab OR 4. In combination with pomalidomide and dexamethasone for members who have received at least two prior therapies, including an immunomodulatory agent and a proteasome inhibitor OR 5. In combination with panobinostat in members who have received at least two prior regimens, including bortezomib and an immunomodulatory agent.

UM ONC_1283	Lenvima (lenvatinib)	Negative change	Add inclusion criteria: 1. RCC - NOTE: The preferred tyrosine kinase inhibitor, per NCH Policies, for first line metastatic RCC is: i.Pazopanib for good risk disease ii.Cabozantinib for intermediate or poor risk disease; a. 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 everolimus as subsequent therapy for clear cell carcinoma 2. HCC- NOTE: The preferred agent, per NCH Policies, for first line therapy of unresectable or metastatic HCC is LENVATINIB.
UM ONC_1283	Lenvima (lenvatinib)	Positive change	Add inclusion criteria: 5. Endometrial Cancer- a. The member has advanced or recurrent microsatellite stable endometrial cancer AND b. Lenvima (lenvatinib) is being used in combination with pembrolizumab as subsequent line of therapy.
UM ONC_1283	Lenvima (lenvatinib)	Positive change	Remove exclusion criteria: 2. Concurrent use with other tyrosine kinase inhibitors (i.e. sorafenib, sunitinib, axitinib). 3. Member with significant cardiovascular impairment: arterial thrombotic event, cardiac dysfunction or hemorrhage, or life-threatening hypertension. 5. Member with proteinuria greater than or equal to 2 grams over 24 hours. 6. Member with gastrointestinal perforation or life-threatening fistula. 7. Member with QT interval prolongation of Grade 3 severity.
UM ONC_1283	Lenvima (lenvatinib)	Negative change	Add exclusion criteria: 4. Max dose 20 mg/day for endometrial cancer.

UM ONC_1089	Libtayo (cemiplimab-rwlc)	Positive change	Remove exclusion criteria: 2. Concurrent use or within 4 weeks prior to first dose of Libtayo (cemiplimab-rwlc) with other immune-modulating agents (e.g., immunosuppressive corticosteroid doses, therapeutic vaccines, cytokine treatments, or agents that target cytotoxic T-lymphocyte antigen 4 (CTLA-4), 4-1BB (CD137), or OX-40, etc.) 3. Significant autoimmune disease that required treatment with systemic immunosuppressive treatments, active infection, history of pneumonitis or solid organ transplant.
UM ONC_1311	Lonsurf (trifluridine/tipiracil)	Negative change	Add inclusion criteria: 1. Colorectal Cancer- b. Lonsurf (trifluridine/tipiracil) is being used as a single agent in members who have progressed through all available regimens except Stivarga and Lonsurf
UM ONC_1311	Lonsurf (trifluridine/tipiracil)	Positive change	Remove inclusion criteria: 2. Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma- Karnofsky performance score ≥60% or ECOG performance score ≤2
UM ONC_1311	Lonsurf (trifluridine/tipiracil)	Positive change	Remove exclusion criteria: 1. Lonsurf (trifluridine/tipiracil) is being used after disease progression with regorafenib. 4.Treatment exceeds the maximum limit of 4 to 80 (20 mg) tablets/month.
UM ONC_1072	Myeloid Growth Factors (Neupogen, Granix, Leukine, Zarxio, Nivestym, Neulasta/Fulphila/Udenyca/Ziextenzo)	Negative change	Add inclusion criteria:NOTE: For members on palliative chemotherapy for recurrent/metastatic disease, NCH encourages dose reduction or cycle lengthening as an alternative to use of an MGF. When dosees reduction is not an option, then short-acting growth factors are preferred, over long acting.
UM ONC_1316	Nerlynx (neratinib)_	Positive change	Add inclusion criteria: 2. Breast Cancer- b. The member has metastatic HER2 positive metastatic breast cancer and Nerlynx (neratinib) is being used in combination with capecitabine and the member has received two or more prior anti-HER-2 based regimens except lapatinib in the metastatic setting.
UM ONC_1312	Odomzo (sonidegib)	Positive change	Add inclusion criteria: a. The member has r metastatic BCC not amenable to curative surgery or radiation therapy
UM ONC_1274	Opdivo (nivolumab)	Positive change	Add inclusion criteria: RCC - ii. IMDC criteria table for risk categories 9. SCLC- a. The member has recurrent/relapsed SCLC

UM ONC_1274	Opdivo (nivolumab)	Positive change	Remove inclusion criteria: SCLC- c. NOTE: When nivolumab is used in combination with ipilimumab, the recommended dose of ipilimumab should not exceed 1 mg/kg every 3 weeks for a maximum of 4 cycles with Nivolumab dosed at 3 mg/kg every 3 weeks.
UM ONC_1274	Opdivo (nivolumab)	Negative change	Add inclusion criteria: d. Opdivo (nivolumab) is being used in combination with Yervoy (ipilimumab) followed by single agent Opdivo AND e. Member has experienced disease progression on or after therapy with sorafenib/ lenvatinib/regorafenib./cabozantinib AND single agent Opdivo (nivolumab).
UM ONC_1216	Perjeta (pertuzumab)	Negative change	Add inclusion criteria: Neoadjuvant & Adjuvant therapy of HER-2 + Breast cancer 3. Pertuzumab + Trastuzumab + Chemotherapy is indicated only in patients with a tumor size 2 cm or higher, node positive disease or ER/PR negative disease. The combination may be used in the neoadjuvant setting. 4. When Pertuzumab + Trastuzumab + Chemotherapy is used in the adjuvant setting, it may be used as the following- a. No neoadjuvant therapy was given OR .b. Neoadjuvant therapy was given and there was no residual disease found in the breast/axillary nodes at surgery. 5. After neoadjuvant therapy, if there is evidence of residual disease in the breast and or axillary nodes, then the Preferred adjuvant drug is Kadcyla.
UM ONC_1362	Polivy (polatuzumab vedotin)	Negative change	Add inclusion criteria: 1. Diffuse Large B-Cell Lymphoma (DLBCL) a. NOTE: Unless contraindicated or not tolerated, the preferred regimens, per NCH Policies, for relapsed/refractory DLBCL are i. R-CHOP/R-CEOP/R-EPOCH AND ii. R-ICE/R-ESHAP/RDHAP OR iii. Gemcitabine containing regimen (i.e. GDP/GEMOX).

UM ONC_1362	Polivy (polatuzumab vedotin)	Positive change	Add inclusion criteria: c. Has failed at least 2 prior therapies, including ALL of the following: i.iv.R-CHOP/R-CEOP/R-EPOCH AND ii.v.R-ESHAP/RDHAP/R-ICE OR iii.vi.Gemcitabine containing regimen (i.e. GDP/GEMOX)
New	Reblozyl (luspatercept)	n/a	n/a
UM ONC_1367	Rozlytrek (entrectinib)	Negative change	Add inclusion criteria: 2. NTRK-Fusion Positive Metastatic Solid Tumors NOTE: The preferred agent, per NCH Policies & NCH Pathway for NTRK gene fusion positive recurrent, advanced, or metastatic solid tumors is Rozlytrek (entrectinib) over Vitrakvi (larotrectinib). The member has locally advanced All the following criteria should be met: a.Member has recurrent/metastatic/unresectable sold tumor with a positive NTRK fusion in the tumor tissue (test confirmation required) b.Member has experienced disease progression on standard/conventional systemic therapy
UM ONC_1367	Rozlytrek (entrectinib)	Negative change	Add inclusion criteria: NSCLC NOTE: The preferred agent, per NCH Policy and NCH Pathway for first line therapy of ROS1 + NSCLC with CNS metastases is Entrectinib; for patients without CNS metastases the preferred agent is crizotinib. b. ROS1 rearrangement-positive tumors with CNS metastases as first-line therapy , or with ROS 1 rearrangement with/without CNS metastases for subsequent line therapy.
UM ONC_1367	Rozlytrek (entrectinib)	Negative change	Add exclusion criteria: 1. Off-label indications for Rozlytrek (entrectinib) in Soft Tissue Sarcoma, Occult Primary, Head and Neck Cancers, Thyroid Cancers, Pancreatic Adenocarcinoma, and ovarian cancers shall be reviewed for appropriateness per National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or other compelling medical literature publications. 2. Rozlytrek (entrectinib) is being used after disease progression with other NTRK-targeted therapy .

UM ONC_1367	Rozlytrek (entrectinib)	Positive change	Remove exclusion criteria: 3.The member has a history of any of the following: a.Symptomatic congestive heart failure or ejection fraction ≤ 50% b.Prolonged QTc interval or risk of torsades de pointes c.Peripheral neuropathy grade ≥ 2 d.a.Known active infections
New	Sarclisa® (isatuximab-irfc)	n/a	n/a
UM ONC_1250	Tafinlar (dabrafenib)	Negative change	Add inclusion criteria: 1.BRAF V600E positive Melanoma - i. NOTE: For stage III melanoma, the preferred agents per NCH Policies & NCH Pathway, for adjuvant therapy are Nivolumab and PembrolizumabIn combination with Mekinist (trametinib) as adjuvant therapy for stage IIIA with sentinel lymph node metastasis > 1 mm during nodal basin ultrasound surveillance or stage IIIB/IIIC after complete lymph node dissection OR ii. NOTE: Fore systemic therapy of metastatic BRAF V600E melanoma the preferred combination, per NCH Policies and NCH Pathway is [Cobimetinib + Venurafenib]
UM ONC_1215	Treanda/Bendeka/Belrapzo (bendamustine)	Negative change	Remove inclusion criteria:1.2.Chronic lymphocytic leukemia/small lymphocytic lymphoma- a. As first-line owith/without ofatumumab, or obinutuzumab b.For relapsed or refractory disease without del(17p)/TP53 mutation in combination with rituximab for members age < 65 years without significant comorbidities.
UM ONC_1215	Treanda/Bendeka/Belrapzo (bendamustine)	Positive change	Add inclusion criteria: 2. Non-Hodgkin's lymphoma- add extra-nodal marginal zone; remove single agent 2nd line;
UM ONC_1215	Treanda/Bendeka/Belrapzo (bendamustine)	Positive change	Remove inclusion criteria:b.Diffuse Large B-Cell Lymphoma-2nd line-remove in non-candidates for high-dose therapy.
UM ONC_1215	Treanda/Bendeka/Belrapzo (bendamustine)	Negative change	Add exclusion criteria: 1. Off-label indications for Treanda/Bendeka/Belrapzo (bendamustine) in multiple myeloma, Waldenstrom's macroglobulemia, and Hodgkin's Lymphoma shall be reviewed for appropriateness per National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or other compelling medical literature publications. .2.Not to be used in members with CrCl < 30 ml/min.

UM ONC_1135	Vectibix panitumumab)	Positive change	Remove inclusion criteria: 1..KRAS/NRAS- Wild Type Metastatic/Recurrent/ Unresectable Colorectal Cancer as Initial therapy (left-sided tumors for colon cancer only)
UM ONC_1135	Vectibix panitumumab)	Positive change	Remove exclusion criteria: 1.Vectibix (panitumumab) is being used for any of the following: b.In combination with FOLFOX as second line therapy
UM ONC_1137	Vidaza (azacitidine) and Dacogen (decitabine)	Negative change	Add inclusion criteria: MDS NOTE: The preferred hypomethylating agent, per NCH Policy & NCH Pathway is Azacitidine ies, for the treatment of MDS; Vidaza (azacitidine) or Dacogen (decitabine) may be used in all subtypes of MDS- Myelodysplastic Syndromes
UM ONC_1137	Vidaza (azacitidine) and Dacogen (decitabine)	Positive change	Remove inclusion criteria: a.The member has ONE of the following myelodysplatic syndrome subtypes: i.Refractory anemia (RA) and refractory anemia with ringed sideroblasts (RARS): if accompanied by neutropenia OR thrombocytopenia OR requiring transfusions ii.Refractory anemia with excess blasts (RAEB) iii.Refractory anemia with excess blasts in transformation (RAEB-T) iv. Chronic myelomonocytic leukemia (CMML)
UM ONC_1137	Vidaza (azacitidine) and Dacogen (decitabine)	Negative change	Add inclusion criteria: 3. Acute Myeloid leukemia (AML) NOTE: The preferred hypomethylating agent, per NCH Policies, for the treatment of AML is AZACITIDINE. a.Vidaza (azacitidine) or Dacogen (decitabine) is being use for AML as the following: i.As a single agent or in combination with venetoclax as induction, post remission consolidation, or salvage therapy NOTE: Azacitidine + Venetoclax regimen is NCH preferred pathway for menbers who are not suitable for intensive therapy OR ii.For FLT3-ITD mutation positive AML, Vidaza (azacitidine) or Dacogen (decitabine) is being as a single agent or in combination with sorafenib for relapsed or refractory disease.

UM ONC_1137	Vidaza (azacitidine) and Dacogen (decitabine)	Positive change	Add inclusion criteria: AML- Vidaza (azacitidine) or Dacogen (decitabine) is being use for AML as the following: i. As a single agent or in combination with venetoclax as induction, post remission consolidation, or salvage therapy NOTE: Azacitidine + Venetoclax regimen is NCH preferred pathway for menbers who are not suitable for intensive therapy OR
UM ONC_1137	Vidaza (azacitidine) and Dacogen (decitabine)	Positive change	Remove exclusion criteria: 1. Vidaza (azacitidine) or Dacogen (decitabine) is being used for RA or RARS not accompanied by neutropenia, thrombocytopenia, clinical hemorrhage requiring platelet transfusions, OR anemia requiring red blood cell transfusions.
UM ONC_1137	Vidaza (azacitidine) and Dacogen (decitabine)	Positive change	Remove inclusion criteria: IPSS TABLE
UM ONC_1250	Tafinlar (dabrafenib)	Negative change	Add exclusion criteria: 1. The member has wild-type BRAF NSCLC or anaplastic thyroid cancer. 2. Disease progression while taking other BRAF inhibitor (i.e. vemurafenib or encorafenib).
UM ONC_1250	Tafinlar (dabrafenib)	Positive change	Remove exclusion criteria: 3. Concurrent use with other chemotherapy, radiation therapy, immunotherapy, biologic therapy, or surgery. 4. Previous treatment with BRAF or MEK inhibitor (i.e. vemurafenib or trametinib).
UM ONC_1350	Vitrakvi (larotrectinib)	Negative change	Add inclusion criteria: NTRK positive Metastatic Solid Tumors- NOTE: The preferred agent, per NCH Policies & NCH Pathway, for NTRK gene fusion positive recurrent, advanced, or metastatic tumors is Rozlytrek (entrectinib) over Vitrakvi (larotrectinib).

UM ONC_1350	Vitrakvi (larotrectinib)	Positive change	Remove inclusion criteria: i. Members have received prior standard therapy OR would be unlikely to tolerate or derive clinical benefit from appropriate standard of care therapy in the following examples: a. Soft Tissue Sarcoma b. Thyroid Carcinoma c. Central Nervous System Cancers d. Colorectal cancers e. Cutaneous Melanoma f. Esophageal and Esophagogastric Junction Cancers g. Gastric Cancer h. Head and Neck Cancers i. Hepatobiliary Cancers j. Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer k. Pancreatic Adenocarcinoma l. Rectal Cancer
UM ONC_1350	Vitrakvi (larotrectinib)	Negative change	Add exclusion criteria: 2.Concurrent use with other anti-cancer therapy.
UM ONC_1350	Vitrakvi (larotrectinib)	Positive change	Remove exclusion criteria: 3. Symptomatic or unstable brain metastases.
UM ONC_1228	Xtandi (enzalutamide)	Negative change	Add inclusion criteria: NOTE: For metastatic castration-sensitive prostate cancer Abiraterone is preferred per NCH Policy and NCH Pathway
UM ONC_1228	Xtandi (enzalutamide)	Negative change	Remove inclusion criteria: ii. Systemic therapy as a single agent for castration-naïve M1 disease after orchiectomy
UM ONC_1201	Yervoy (Ipilimumab)	Negative change	Add inclusion criteria: NOTE: The PREFERRED dose of Ipilimumab, whenever used in combination with nivolumab, is 1 mg/kg, except for Small Cell Lung Cancer.
UM ONC_1201	Yervoy (Ipilimumab)	Negative change	Add inclusion criteria: Melanoma- a. NOTE : The PREFERRED drugs per NCH Policies & NCH Pathway, for the adjuvant therapy of completely resected stage III melanoma areis Nivolumab and Pembrolizumab.

UM ONC_1201	Yervoy (Ipilimumab)	Positive change	Remove inclusion criteria: ALL ECOG performance status 0-2
UM ONC_1201	Yervoy (Ipilimumab)	Positive change	Add inclusion criteria: RCC IMDC criteria
UM ONC_1201	Yervoy (Ipilimumab)	Positive change	Add inclusion criteria: Hepatocellular Carcinoma (HCC) a. Member has recurrent/metastatic/inoperable HCC, AND b. Yervoy is being used in combination with Opdivo (nivolumab) AND c. Member has experienced disease progression on or after therapy with sorafenib/ lenvatinib/regorafenib./cabozantinib AND single agent Opdivo (nivolumab).
UM ONC_1208	Zytiga or Yonsa (abiraterone acetate)	Negative change	Add inclusion criteria: NOTES: The preferred agent, per NCH Policies and NCH Pathway, for metastatic castrate sensitive prostate cancer (M1 disease), is Abiraterone Acetate over Enzalutamide. Generic Abiraterone is preferred when available/possible. Abiraterone is NOT indicated for Castrate-Resistant NON-METASTATIC prostate cancer (M0 disease with no radiographically visible metastases)
UM ONC_1208	Zytiga or Yonsa (abiraterone acetate)	Negative change	Remove inclusion criteria: Metastatic Castrate-Resistant Prostate Cancer as secondary hormone therapy in combination an LHRH agonist or antagonist