Policy	Drug(s)	Type of Change	Brief Description of Policy Change
New	Margenza (margetuximab-cmkb)	n/a	n/a
UM ONC_1038	Emend (Aprepitant oral or Fosaprepitant), Cinvanti (aprepitant injection) and Varubi (rola	Negative change	Add inclusion criteria: 1.Note: Per NCH policy, intravenous Emend (fosaprepitant) is preferred over oral Emend (aprepitant), Cinvanti (aprepitant injection), and Varubi (rolapitant oral). Remove Varubi injection since no longer on the market.
UM ONC_1039	Faslodex (fulvestrant)	Positive change	Add inclusion criteria: Used as a single agent
UM ONC_1041	LHRH agonists and antagonist	Negative change	Add inclusion criteria: Add relugolix as non-preferred Prostate cancer 1.Note#2: For ADT- Androgen Deprivation Therapy- in prostate cancer,the oral LH-RH analog relugolix is not recommended per NCH Pathway and NCH Policy. Preferred alternatives are described above in Note#1. Thie recommendation is based on a lack of Overall Survival benefit with relugolix over leuprolide. Breast cancer 1.Eligard/Lupron Depot (J9217 leuprolide 7.5 mg or 22.5 mg) may beis being used in combination with endocrine therapy (Tamoxifen or an aromatase inhibitor), with or without additional anti-cancer therapy , in perimenopausal /premenopausal women with ER/PR+ breast cancer whenever ovarian suppression/ovarian ablation is clinically indicated.
UM ONC_1042	Somatostatin Analog: Sandostatin (octreotide) and Somatuline™ (lanreotide)	Negative change	Update policy title to: Somatostatin Analog: Sandostatin™/Bynfezia Pen™/ Sandostatin LAR Depot™ (octreotide) and Somatuline Depot™ (lanreotide) Add inclusion criteria: Note: The preferred Somastatin Analog is Sandostatin IV/SC or LAR Depot (octreotide) over Bynfezia Pen (octreotide) or Somatuline Depot (lanreotide). Somatuline Depot (lanreotide) may be used in members with contraindication/intolerance to OR failure of Sandostatin IV/SC or LAR Depot (octreotide).
UM ONC_1130	Alimta (pemetrexed)	Positive change	Remove inclusion criteria: NSCLC: i.First line therapy for EGFR & , ALK , ~~ROS1, and other driver mutation~~ negative disease in combination with carboplatin/cisplatin and pembrolizumab OR ii.First line therapy ~~for EGFR, ALK, ROS 1, and other driver mutation negative disease~~ in combination with carboplatin/cisplatin OR iii.Subsequent therapy ~~for EGFR/ALK/ROS1 positive disease in members that have received targeted therapies for any of the above 3 genomic alterations either as a single agent, or~~in combination with carboplatin/cisplatin v.Continuation maintenance therapy as a single agent or in combination with pembrolizumab following first-line therapy with [pembrolizumab +, pemetrexed + cisplatin /carboplatin].
UM ONC_1130	Alimta (pemetrexed)	Positive change	Remove exclusion criteria: 1.Off-label indications for Alimta (pemetrexed) in bladder 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.For member with NSCLC, Alimta (pemetrexed) will be used for any of the following: a.Squamous cell histology b.As adjuvant therapy for stage IA
UM ONC_1132	Rituxan Products (Rituxan, Rituxan Hycela, Truxima, Ruxience, Riabni)	Positive change	Add inclusion criteria: Add Riabni biosimilar B. CD-20 positive B-Cell Non-Hodgkin's Lymphoma (NHL) c.Maintenance therapy: 1. For up to two years for Indolent B-Cell Lymphomas(Follicular B Cell Lymphoma, and all subtypes of Marginal Zone Lymphoma C. CLL and Hodgkin's Lymphoma- As maintenance therapy for up to 2 years E. ITP: Platelet count is < 30,000
UM ONC_1132	Rituxan Products (Rituxan, Rituxan Hycela, Truxima, Ruxience, Riabni)	Positive change	Remove inclusion criteria: Remove preferred Rituxan Hycela CLL: In combination with Venetoclax ITP: Platelet count is < 25,000
UM ONC_1135	Vectibix (panitumumab)	Negative change	Add inclusion criteria: a.In combination with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or FOLFIRI (fluorouracil, leucovorin, and irinotecan) for members who have not received prior therapy containing either panitumumab or cetuximab OR as Therapy for KRAS/NRAS/BRAF wild-type gene and left-sided only tumors in combination with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or FOLFIRI.
UM ONC_1135	Vectibix (panitumumab)	Negative change	Remove inclusion criteria: b.In combination with irinotecan or FOLFIRI (fluorouracil, leucovorin, and irinotecan) for disease previously treated with oxaliplatin based chemotherapy OR c.In combination with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) regimen for disease previously treated with irinotecan based chemotherapy
UM ONC_1135	Vectibix (panitumumab)	Positive change	Add inclusion criteria: c.Vectibix (panitumumab) may be used as subsequent therapy in combination with encorafenib for patients with unresectable/ metastatic disease (BRAF V600E mutation positive).
UM ONC_1138	Erythropoiesis Stimulating Agents (ESA)	Negative change	Add inclusion criteria: B.Chemotherapy induced anemia (CIA) 1.ESA is being used in members with symptomatic anemia with solid tumors or non-myeloid malignancies receiving myelosuppressive chemotherapy without curative intent
UM ONC_1177	Gleevec (imatinib mesylate)	Negative change	Add inclusion criteria: Use of generic imatinib (instead of brand) before other TKIs. 7.Gastrointestinal stromal tumors (GIST) a.NOTE: The preferred agent, per NCH Pathway & NCH Policy, for adjuvant therapy (for surgically resected disease) and for primary/ initial therapy of unresectable/recurrent/metastatic disease is generic IMATINIB. i.As primary or subsequent therapy for metastatic/unresectable/recurrent disease OR ii.For Preoperative (neoadjuvant)/postoperative (adjuvant) therapy of resected disease
UM ONC_1181	Parenteral Iron Products	Negative change	Add inclusion criteria: B.Iron Deficiency v.An exception to the Hgb requirement can be made if the serum ferritin level is < 50 ng/ml and/or the transferrin saturation TSAT is < 10%
UM ONC_1201	Yervoy (ipilimumab)	Negative change	Add inclusion criteria: E.Colorectal Cancer 1.NOTE: Yervoy (ipilimumab) is not a preferred drug per NCH Policy or NCH Pathway for unresectable/metastatic/recurrent microsatellite instability-high (MSI-H) or mismatch repair deficient [dMMR] colorectal cancer. The preferred drug in this setting in single agent pembrolizumab. Please refer to UMC ONC_ 1263 Keytruda (pembrolizumab) policy. F.Hepatocellular Carcinoma (HCC) 1.NOTE: Yervoy (ipilimumab) is not a preferred drug per NCH Policy or NCH Pathway for the initial or subsequent treatment of hepatocellular carcinoma. Please refer to the NCH Pathway document for the most current recommended therapies for hepatocellular carcinoma.

UM ONC_1203	Adcetris (brentuximab)	Negative change	Add inclusion criteria: B.Classical Hodgkin Lymphoma 1.NOTE: The preferred regimen for first line therapy in stage III and IV classical Hodgkin's Lymphoma per NCH Policies and NCH Pathways, is ABVD (doxorubicin, bleomycin, vinblastine, dacarbazine) except in members with contraindications or intolerance to Bleomycin (e.g. lung disease, prior smoking history) AND IPS- International Progrnostic Score of 2-7 (see below). - International Prognostic Score in Hodgkin Lymphoma - IPS Score: 5 year Freedom From Progression (FFP) and Overall Survival (OS)
UM ONC_1203	Adcetris (brentuximab)	Negative change	Add exclusion criteria: C.Treatment with Adcetris (brentuximab vedotin) exceeds the maximum duration limit of 6 month cycles as a part of AAVD (12 doses for first line treatment of Hodgkin's Disease) OR exceeds 16 cycles for refractory/relapsed disease/consolidation treatment after HSCT OR exceeds 8 doses for previously untreatedCD-30 + T Cell Lymphoma
UM ONC_1208	Zytiga or Yonsa (abiraterone acetate)	Negative change	Add inclusion criteria: 2.Prostate Cancer a.NOTES: For members who have not previously received Zytiga (abiraterone), Erleada (apalutamide), or Xtandi (enzalutamide), the preferred first line oral agent, per NCH Policies and NCH Pathway, for metastatic castrate sensitive prostate cancer (M1 disease) is Zytiga (abiraterone acetate) over Xtandi (Eenzalutamide).Generic abiraterone 250 mg tablet is preferred over abiraterone 500 mg tablet when available/possible.
UM ONC_1218	Provenge (sipuleucel-T)	Negative change	Add inclusion criteria: B.Prostate Cancer NOTE #1: Provenge is a Non-Preferred therapy for meastatic castrate-resistant prostate cancer per NCH Policy & NCH Pathway. NOTE #2:The preferred agents, per NCH Policies, for any first line therapy of castration-resistant ~~distant~~ metastatic (M1) disease include Androgen Deprivation Therapy, with or without Zytiga (abiraterone) OR Taxotere (docetaxel), over Provenge (sipuleucel-T). ~~As per NCH Policy and NCH Pathway, Provenge (sipuleucel-T) is not a preferred agent for castration resistant metastatic prostate cancer.~~
UM ONC_1218	Provenge (sipuleucel-T)	Positive change	Remove inclusion criteria: 2.The member has castration-resistant distant metastatic prostate cancer, is asymptomatic or minimally symptomatic, and does not have visceral disease (lung, liver, or brain metastases) AND 3.The member has a life expectancy of > 6 months AND 4.The member's ECOG performance status is 0-1.
UM ONC_1218	Provenge (sipuleucel-T)	Positive change	Remove exclusion criteria: A.The member has stage 1-3 prostate cancer. B.The member has cancer related bone pain requiring systemic corticosteroid, opioid analgesics, or bone modifying agents (i.e. bisphosphonates) within previous 28 days. C.The member received chemotherapy within the previous 3 months. D.Provenge (sipuleucel-T) is being used concurrently with immunosuppressive agents, chemotherapy, Zytiga (abiraterone), or anti-androgens (e.g. enzalutamide, apalutamide and darolutamide). E.Treatment with Provenge (sipuleucel-T) exceeds the recommended course of therapy of 3 complete doses given at approximately 2-week intervals.
UM ONC_1218	Provenge (sipuleucel-T)	Negative change	Add exclusion criteria: A.Provenge is Non-Preferred per NCH Policy
UM ONC_1224	Kyprolis (carfilzomib)	Negative change	Add inclusion criteria: 1.NOTE: Per NCH policy and pathway, the preferred Proteasome inhibitor is Velcade (bortezomib) over Kyprolis (carfilzomib) or Ninlaro (ixazomib) for all settings in the treatment of multiple myeloma, unless there is contraindication/intolerance or failure to Velcade (bortezomib). Please refer to UM ONC_1136 Velcade (bortezomib) policy. 2.NOTE: For initial therapy of newly diagnosed multiple myeloma, both transplant eligible and transplant ineligible, Kyprolis (carfilzomib) based regimens are non-preferred per NCH Pathway & NCH Policy: Please refer to the NCH Pathway document for preferred/Level 1 recommended therapies for the initial treatment of Multiple Myeloma. 3.For relapsed or refractory disease, Kyprolis (carfilzomib) may be usedIn combination with daratumumab +/- dexamethasone.
UM ONC_1235	Doxil or Lipodox (liposomal doxorubicin)	Negative change	Remove inclusion criteria: 4.Multiple Myeloma a.NOTE: Please refer to NCH Pathway for L1 preferred regimens/agents for initial and subsequent therapy for Multiple Myeloma.
UM ONC_1235	Doxil or Lipodox (liposomal doxorubicin)	Positive change	Remove exclusion criteria: 2.Members with cardiomyopathy and those receiving concurrent radiation over the heart. 3.Dosing exceeds single dose limit of Doxil/Lipodox (liposomal doxorubicin) 50 mg/m2. 4.Dosing exceeds the total cumulative doses of 550 mg/m2.
UM ONC_1237	Cometriq or Cabometyx (cabozantinib)	Negative change	Add inclusion criteria: 2. Thyroid Cancer a. NOTE: The preferred oral tyrosine kinase inhibitor (TKI) for use in metastatic medullary thyroid cancer is Caprelsa (vendatinib) and the preferred TKI for differentiated thyroid cancers (e.g. papillary, follicular, or Hurthle cell thyroid cancer) is Lenvima (Lenvatinib) over Cometriq (cabozantinib). 3.Kidney Cancer: Used as monotherapy in first and subsequent line of therapy. 4.Hepatocellular Carcinoma (HCC) a.NOTE: The preferred tyrosine kinase inhibitor, per NCH Policy & NCH Pathway, for subsequent line therapy of unresectable or metastatic HCC is REGORAFENIB. This recommendation is based on lack of Level 1 evidence supporting the superior efficacy of cabozantinib over regorafenib. b.a.The member has HCC and CABOMETYX (cabozantinib) is being used as a single agent for unresectable or metastatic disease in members with Child-Pugh Class A only and who have been previously treated with 2 prior systemic therapies including sorafenib.
UM ONC_1238	Kadcyla (ado-trastuzumab emtansine)	Negative change	Add inclusion criteria: For Neoadjuvant/adjuvant : < 2 cm OR ER/PR positive OR NODE negative; used as a single agent
UM ONC_1242	Jakafi (ruxolitinib)	Positive change	Remove inclusion criteria: Myelofibrosis c.The member has splenomegaly and symptoms (i.e. night sweats, itching, abdominal discomfort, pain under ribs on left, feeling of fullness, or muscle/bone pain) AND d.The member has intermediate (2 prognostic factors) or high-risk (3 or more prognostic factors) myelofibrosis. The prognostic factors include the following: i.Age > 65 years ii.Hemoglobin < 10 g/l iii.Leukocyte > 25 × 109/l iv.Circulating blasts ≥ 1% blasts v.Platelet count <100 × 109/l vi.RBC transfusion need vii.b.Unfavorable karyotype +8,–7/7q–, i(17q), inv(3), –5/5q–,12p–, 11q23

UM ONC_1242	Jakafi (ruxolitinib)	Positive change	Remove exclusion criteria: 2.Member with serious active infections.
UM ONC_1258	Gilotrif (afatinib)	No Changes	n/a
UM ONC_1259	Gazyva (obinutuzumab)	No Changes	n/a
UM ONC_1260	Beleodaq (belinosat)	Positive change	Remove exclusion criteria: 1.Off-label indications for Beleodaq (belinosat) in primary cutaneous lymphomas.
UM ONC_1274	Opdivo (nivolumab)	Negative change	Add inclusion criteria: Melanoma: a.As a single agent for adjuvant therapy of high-risk Stage III melanoma following complete resection of the primary tumor and a complete regional lymph node dissection. Maximum duration of therapy is one year. D. Renal Cell Carcinoma 1.The member has recurrent/metastatic/surgically unresectable stage IV disease and Opdivo (nivolumab) is being used for ONE of the following: a.As first line therapy in combination with Yervoy (ipilimumab) for IMDC Intermediate or Poor Risk disease. NOTE: In the above setting,, ipilimumab is dosed at 1 mg/kg every 3 weeks xx 4 cycles only, nivolumab is dosed as 3 mg/kg every 3 weeks, 4 followed by single agent Opdivo (nivolumab) either as 240 mg every 2 weeks or 480 mg every 4 weeks ~~for intermediate or poor risk disease as defined by the IMDC (International Metastatic Renal Cell Carcinoma Database Consortium).~~
UM ONC_1324	Kymriah (tisagenlecleucel)	Negative change	Add inclusion criteria: 2.Acute Lymphoblastic Leukemia (ALL) a. Kymriah (tisagenlecleucel) is being used in member 25 years old or younger 3. B-Cell Lymphomas a.i. Kymriah (tisagenlecleucel) Mmay be used for members who are 18 years of age or older, with Diffuse Large B-Cell Lymphoma, transformed Follicular Lymphoma, high-grade B-cell lymphoma with MYC rearrangement plus rearrangement of BCL2, BCL6, or both genes (i.e., double- or triple-hit lymphoma) with confirmed documentation of CD19 tumor expression. AND b.Members must have previously received at least two lines of therapy, including rituximab and an anthracycline AND c.Either having failed autologous Hematopoietic stem cell transplantation (ASCT), or being ineligible for or not consenting to ASCT.
UM ONC_1324	Kymriah (tisagenlecleucel)	Positive change	Remove inclusion criteria: B-Cell lymphoma a.The member has grade 1-2 relapsed or refractory follicular lymphoma or relapsed/refractory DLBCL- Diffuse Large B-Cell Lymphoma AND member has experienced disease progression after two or more lines of systemic therapy (if tisagenlecleucel or axicabtagene ciloleucel not previously given).
UM ONC_1324	Kymriah (tisagenlecleucel)	Negative change	Add exclusion criteria: 2.Previous allogeneic transplant 3.Active CNS involvement with lymphoma
UM ONC_1329	Yescarta (axicabtagene ciloleucel)	Negative change	Add inclusion criteria: 2.Non-Hodgkin Lymphomas (NHL) a.The member has one of the following aggressive , CD-19 positive NHL
UM ONC_1329	Yescarta (axicabtagene ciloleucel)	Positive change	Remove inclusion criteria: c.The member had prior therapy with anti-CD20 monoclonal antibody (i.e. rituximab or obinutuzumab) AND an anthracycline (i.e. CHOP) containing chemotherapy regimen.
UM ONC_1329	Yescarta (axicabtagene ciloleucel)	Positive change	Remove exclusion criteria: 2.History or presence of any ONE of the following are excluded: a.Prior allogeneic HSCT or a history of central nervous system lymphoma b.Presence of fungal, bacterial, viral, or other infection that is uncontrolled or requiring IV antimicrobials for management. c.History or presence of CNS disorder such as seizure disorder, cerebrovascular ischemia/hemorrhage, dementia, cerebellar disease, or any autoimmune disease with CNS involvement d.History of hepatitis infection: history of hepatitis B or hepatitis C is permitted if the viral load is undetectable. 2.Concurrent use with other systemic immunosuppressive therapy or live virus vaccines. 3.Dosing exceeds single dose limit of Yescarta (axicabtagene ciloleucel) 2 X 108 CAR-positive viable T-cells.
UM ONC_1329	Yescarta (axicabtagene ciloleucel)	Negative change	Add exclusion criteria:3.No documented CD-19 status in lymphoma cells.
UM ONC_1365	Xpovio (selinexor)	Negative change	Add inclusion criteria: 2.Multiple Myeloma a.Xpovio(Selinexor) may be used as a single agent for a member with relapsed/refractory multiple myeloma who has experienced disease progression on 3 different classes of agents including one proteasome inhibitor(e.g. bortezomib, carfilzomib, ixazomib), one immunomodulatory agent (e.g. lenalidomide, thalidomide, pomalidomide) and daratumumab. 3.Diffuse Large B-cell Lymphoma (DLBCL) a.Xpovio (selinexor) may be used as a single agent in a member with relapsed/refractory diffuse large B-Cell Lymphoma, that has progressed on 2 or more lines of therapy AND has either failed autologous stem-cell transplant or was not eligible/suitable (based on clinical assessment) for an autologous stem-cell transplant.
UM ONC_1365	Xpovio (selinexor)	Positive change	Remove inclusion criteria: 2. MM a. Member has relapsed/refractory multiple myeloma and has received prior therapy with Velcade (bortezomib), Kyprolis (carfilzomib), Revlimid (lenalidomide), Pomalyst (pomalidomide), Darzalex (daratumumab), glucocorticoids, and an alkylating agent AND Xpovio (selinexor) is being used as a single agent. 3.Diffuse Large B-cell Lymphoma (DLBCL) a.Member has relapsed or refractory diffuse large B-cell Lymphoma, that has progressed on 2 or more prior therapies, AND b. Xpovio (selinexor) will be used as a single agent.
UM ONC_1413	Tecartus (brexucabtagene autoleucel)	Negative change	Add inclusion criteria: B.Mantle Cell Lymphoma Tecartus (brexucabtagene autoleucel) will be used as a single agent in members 18 years or older with relapsed/refractory Mantle Cell Lymphoma that has progressed on 2 prior, including a chemo-immunotherapy regimen (e.g. R-CHOP or BR) and a Bruton Tyrosine Kinase inhibitor (e.g. ibrutinib, acalabrutinib, or zanubrutinib). Member should have confirmed CD-19+ Mantle Cell Lymphoma.

UM ONC_1413	Tecartus (brexucabtagene autoleucel)	Positive change	Remove exclusion criteria: A.Tecartus (brexucabtagene autoleucel) is being used after disease progression with the same regimen or prior CAR therapy or other genetically modified T cell therapy. B.Concurrent use with other systemic immunosuppressive therapy or live virus vaccines. C.Dosing exceeds single dose limit of Tecartus (brexucabtagene autoleucel) 2 × 108 chimeric antigen receptor (CAR)-positive viable T cells (approximately 68 mL). IV. MEDICATION MANAGEMENT A.Grade 3 or 4 febrile neutropenia is 6% (low risk level). B.The frequency of emesis is 13% (low risk level).
UM ONC_1361	Erwinaze (asparaginase Erwinia chrysanthemi)	Negative change	Add inclusion criteria: