Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
UM ONC_1063	Oncaspar (pegaspargase)	Negative change	Add inclusion criteria: 1. NOTE: Per NCH Policy & NCH Pathway, Asparlas (calaspargase pegol-mknl) is preferred over Oncaspar (pegasparagase) for use in ALL as a part of anti-leukemia therapy. Rationale: AALL07P4 clinical trial results demonstrated no substantial difference in event free survival using Asparlas in comparison to patients treated with pegaspargase in the treatment of ALL. Please refer to UM ONC_1352 Asparlas (calaspargase pegol-mknl) policy.	More Cost Effective Alternative(s)
UM ONC_1180	Immune Globulin (IG)	Negative change	Add inclusion criteria: B.Non- Familial/Acquired/Secondary Hyogammaglobulinemia (e.g.e.g., that is associated with Chronic Lymphocytic Leukemia (CLL), Multiple Myeloma, or post hematopoietic stem cell transplant ~~other hematologic malignancies~~	Per Compendia Listing
UM ONC_1180	Immune Globulin (IG)	Positive change	Add inclusion criteria: a.For initial requests: The member has a documented IgG level < 600 mg/dL within the last 4 weeks OR a documented history of frequent sino-bronchial, skin, or other site bacterial infections, OR is clinically felt to be immunocompromised.	Per Compendia Listing
UM ONC_1180	Immune Globulin (IG)	Positive change	Remove inclusion criteria: For continuation requests: IgG level ≤ 1,000 mg/dL within the last 4 weeks.	Per Compendia Listing
UM ONC_1228	Xtandi (enzalutamide)	Negative change	Add inclusion criteria: b.Xtandi (enzalutamide) may be used in combination with an LH-RH analog (ADT- Androgen Deprivation Therapy) for members with castration-resistant distant metastatic (M1) disease who experience disease progression on abiraterone AND member has not previously received Xtandi (enzalutamide).	More Cost Effective Alternative(s)
UM ONC_1234	Zevalin (ibritumomab tiuxetan)	No Clinical Changes	N/A	N/A
UM ONC_1243	Nplate (romiplostim)	Positive change	Add inclusion criteria: 1.The member has a diagnosis of relapsed/refractory chronic ITP AND the member has had an insufficient therapeutic response (defined by failure of platelet count to increase and stay above 30,000/mm3), intolerance to, or contraindications to corticosteroids, AND/OR immunoglobulin (IVIG), AND/OR rituximab, AND/OR splenectomy.	Per Compendia Listing
UM ONC_1244	Promacta (eltrombopag)	Positive change	Add inclusion criteria: B.Chronic Idiopathic Thrombocytopenic Purpura (ITP) 1.The member has a diagnosis of relapsed/refractory chronic ITP with an insufficient response to previous therapy including corticosteroids, immunoglobulins (IVIG), and Rituxan (rituximab)/splenectomy.	Per Compendia Listing
UM ONC_1244	Promacta (eltrombopag)	Positive change	Remove inclusion criteria: C.Aplastic Anemia 2.Promacta (eltrombopag) may be used as a single agent ~~in members who have not received prior immunosuppressive therapy with Atgam (anti-thymocyte globulin), Campath (alemtuzumab), or high-dose Cytoxan (cyclophosphamide).~~	Per Compendia Listing
UM ONC_1262	Imbruvica (ibrutinib)	Positive change	Add inclusion criteria: B.Mantle Cell Lymphoma (MCL) 1.The member has a diagnosis of relapsed or refractory MCL that has failed or has progressed on first line chemotherapy/chemo-immunotherapy AND 2.Imbruvica (ibrutinib) will be used as a single agent or in combination with rituximab/a rituximab biosimilar product.	Per Compendia Listing
UM ONC_1262	Imbruvica (ibrutinib)	Negative change	Add inclusion criteria: C.Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) 1. NOTE: The preferred Bruton tyrosine kinase (BTK) inhibitor agent per NCH policy & NCH Pathway, for initial/subsequent therapy of CLL/SLL, is Calquence (acalabrutinib) over Imbruvica (ibrutinib), except when the member is intolerant to or has a contraindication to Calquence (acalabrutinib). Please refer to UM ONC_1331 Calquence (acalbrutinib) policy. 2.Imbruvica (ibrutinib) use in combination with an anti-CD20 antibody [e.g. Rituxan (rituximab) or Gazyva (obinutuzumab)] is not supported per NCH policy/NCH Pathway. This is based on the lack of benefit from the addition of rituximab to ibrutinib compared to ibrutinib alone.	Per NCH L1 Pathway
UM ONC_1262	Imbruvica (ibrutinib)	Positive change	Remove inclusion criteria: C.Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Per NCH Policy and NCH Pathway, single agent Imbruvica (ibrutinib) is considered as effective as [Imbruvica(ibrutinib) + an anti-CD20 antibody e.g. rituximab or obinutuzumab].	Other: Sentence replaced with the above
UM ONC_1262	Imbruvica (ibrutinib)	Negative change	Add exclusion criteria: C.Dosing exceeds single dose limit of Imbruvica (ibrutinib) 560 mg (for MCL and MZL) or 420 mg (for CLL/SLL, and WM). D.Treatment exceeds the maximum limit of 120 (140 mg) or 240 (70 mg) capsules a month; 120 (140 mg), 30 (280 mg), 30 (420 mg), 30 (560 mg) tablets a month.	Per FDA labeling
UM ONC_1263	Keytruda (pembrolizumab)	Positive change	Add inclusion criteria: Q.Triple Negative Breast Cancer (TNBC) 1.Keytruda may be used in combination with chemotherapy for any of the following: a.As neoadjuvant/adjuvant therapy in members with newly diagnosed high-risk early-stage TNBC (a tumor size >1 cm but ≤2 cm in diameter with nodal involvement or tumor size >2 cm in diameter regardless of nodal involvement) AND the members have not received prior checkpoint inhibitor (PD-1/PD-L1) therapy, regardless of tumor PD-L1 expression OR 1.b. ~~Keytruda (pembrolizumab) may be used in combination with chemotherapy i~~In members with locally recurrent unresectable or metastatic TNBC whose tumors express PD-L1 with a Combined Positive Score (CPS) ≥10.	New FDA Indication
UM ONC_1303	Xermelo (telotristat ethyl)	Positive change	Remove inclusion criteria: B.Neuroendocrine Tumors c.The member has experienced an inadequate control of his/her diarrhea with somatostatin analog therapy, ~~defined as a baseline stool frequency of ≥ 4 bowel movements a day.~~	Per Compendia Listing

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UM ONC_1306	Bavencio (avelumab)	Negative change	Add inclusion criteria: C.Metastatic Urothelial Carcinoma including carcinomas of the upper Genito-Urinary Tract & Urethra 1.Maintenance Therapy after systemic chemotherapy: Member has metastatic urothelial carcinoma and has experienced CR/PR/SD with 4-6 cycles of first line cisplatin/carboplatin + gemcitabine chemotherapy, AND Bavencio(avelumab) is being used as a single agent. 2.For clinical setting other than maintenance therapy: NOTE: Keytruda (pembrolizumab) is the preferred agent per NCH Policy & NCH Pathway, over other Check-Point Inhibitors (PD-1 or PD-L1 inhibitors i.e. Opdivo, Tecentriq, Bavencio, Imfinzi), for second line therapy of metastatic urothelial carcinoma following platinum containing therapy, or for first line therapy if platinum based therapy is contraindicated regardless of the PD-L1 status; the member should not have received prior therapy with a Check-Point Inhibitor. This recommendation is based on the fact that only Keytruda has Level 1 evidence in this setting showing a survival advantage. ~~please refer to NCH Pathway for recommended agents/regimens for metastatic urothelial carcinoma in settings other than maintenance therapy as described above.~~ D.Renal Cell Carcinoma (RCC) 1.NOTE: Avelumab + axitinib is a non-preferred regimen for metastatic renal cell carcinoma per NCH Policy & NCH Pathway. Opdivo (nivolumab)- given as a single agent or in combination with 4 cycles of Ipilimumab at 1mg/kg- is the preferred agent/regimen over other regimens containing PD-1 or PD-L1 inhibitors (e.g. [Avelumab + Axitinib] & [Pembrolizumab + Axitinib]) for metastatic renal cell carcinoma. This recommendation is based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) showing superior outcomes with [axitinib+pembrolizumab] compared to [ipilimumab+nivolumab]. ~~please refer to NCH Pathway for recommended agents/regimens for metastatic renal cell carcinoma.~~	Per Clinical Trial Analysis/Criteria
UM ONC_1310	Kisqali (ribociclib)	Positive change	Add inclusion criteria: B.Breast Cancer 1.Note: Per NCH policies and NCH L1 Pathways, Verzenio (abemaciclib) and/or Kisqali (ribociclib) are the preferred CDK4/6 inhibitors for postmenopausal women or premenopausal woman treated with ovarian oblation/suppression with advanced/metastatic breast cancer in any of the following settings:	Per Compendia Listing
UM ONC_1323	Idhifa (enasidenib)	No Clinical Changes	N/A	N/A
UM ONC_1325	Mylotarg (gemtuzumab ozogamicin)	No Clinical Changes	N/A	N/A
UM ONC_1328	Verzenio (abemaciclib)	No Clinical Changes	N/A	N/A
UM ONC_1331	Calquence (acalbrutinib)	Negative change	Add inclusion criteria: B.Mantle Cell Lymphoma (MCL) 2.Calquence (acalabrutinib) may be used as monotherapy in relapsed/refractory Mantle Cell Lymphoma if the member has intolerance/contraindication to Imbruvica (ibrutinib). C. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma 1. NOTE: The preferred Bruton tyrosine kinase (BTK) inhibitor agent per NCH policy & NCH Pathway, for initial/subsequent therapy of CLL/SLL, is Calquence (acalabrutinib) over Imbruvica (ibrutinib), except when the member is intolerant to or has a contraindication toCalquence (acalabrutinib) .	Per NCH L1 Pathway
UM ONC_1333	Erleada (apalutamide)	No Clinical Changes	N/A	N/A
UM ONC_1334	Doptelet (avatrombopag)	Negative change	Add inclusion criteria: C.Idiopathic Thrombocytopenia Purpura (ITP) 3.Platelet count ≤ 30,000/mm3 prior to start of therapy.	Per Compendia Listing
UM ONC_1343	Mulpleta (lusutrombopag)	Negative change	Add exclusion criteria: A.Use after failure with Doptelet (avatrombopag) for thrombocytopenia in chronic liver disease.	Per Compendia Listing
UM ONC_1361	Erwinaze and Rylaze (asparaginase Erwinia chrysanthemi and recombinant- rywn)	Positive change	Add inclusion criteria: B.Acute Lymphoblastic Leukemia (ALL) 1.NOTE: Asparlas (calaspargase pegol-mknl) is preferred over Erwinaze and Rylaze (asparaginase Erwinia chrysanthemi and recombinant- rywn) in the treatment of ALL unless the member has a history of a hypersensitivity reaction or other adverse effects from Asparlas (calaspargase pegol-mknl). Please refer to UM ONC_1352 Asparlas (calaspargase pegol-mknl) policy. 2. Erwinaze and Rylaze (asparaginase Erwinia chrysanthemi and recombinant- rywn) may be used in members with a.Philadelphia chromosome-negative ALL/Philadelphia chromosome positive ALL as a part of a multi-agent chemotherapy regimen.	New FDA Drug
UM ONC_1361	Erwinaze and Rylaze (asparaginase Erwinia chrysanthemi and recombinant- rywn)	Negative change	Add exclusion criteria: A. Erwinaze and Rylaze (asparaginase Erwinia chrysanthemi and recombinant- rywn) is being used after disease progression with the same regimen. B.Dosing exceeds single dose limit of Erwinaze (asparaginase Erwinia chrysanthemi) 25,000/m2 International Units or Rylaze (asparaginase Erwinia chrysanthemi recombinant- rywn) 25 mg/m2.	Per FDA labeling

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UM ONC_1363	Nubeqa (darolutamide)	Positive change	Remove inclusion criteria: B.Prostate Cancer a.Non-Metastatic Castration – Resistant Prostate cancer, (M0) disease, ~~with a baseline PSA level of at least 2 ng/ml~~, a PSA doubling time of 10 months or less, AND the absence of documented metastases to any site by conventional imaging (pelvic lymph nodes below aortic bifurcation < 2 cm are allowed), AND b.Nubeqa (darolutamide) will be used in combination with an LHRH analog (ADT- Androgen Deprivation Therapy).	Per FDA labeling
UM ONC_1378	Ayvakit (avapritinib)	Positive change	Add inclusion criteria: C.Advanced Systemic Mastocytosis (AdvSM) 1.Ayvakit (avapritinib) will be used as monotherapy in a member with aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL) and the member's platelet count is≥ 50 × 109/L prior to start of therapy.	Per FDA labeling
UM ONC_1378	Ayvakit (avapritinib)	Negative change	Add exclusion criteria: D.Dosing exceeds single dose limit of Ayvakit (avapritinib) 300 mg (for GIST) and 200 mg (for AdvSM). E.Treatment exceeds the maximum limit of 30 (25 mg), 30 (50 mg), 90 (100 mg), 30 (200 mg), or 30 (300 mg) tablets/month.	Per FDA labeling
UM ONC_1381	Padcev (enfortumab vedotin-ejfv)	Positive change	Add inclusion criteria: B.Urothelial Cancer 1. b.Have previously received Immune Checkpoint Inhibitor therapy and are ineligible for platinum-based therapy	New FDA Indication
UM ONC_1426	Pepaxto (melphalan flufenamide)	Negative change	Add inclusion criteria: Multiple Myeloma In light of the suspension of clinical trials due to an increased risk of death, New Century Health now recommends that Pepaxto be removed from formularies. Likewise, per NCH Policy, Pepaxto is Not Recommended for use. Patient receiving clinical benefit from Pepaxto may continue should they and their physician mutually agree it is in their best interest following a discussion of the risks.A Please refer to the NCH Pathway document for the recommended/preferred regimens in the treatment of relapsed/refractory Multiple Myeloma.	Not recommended per FDA safety alert
UM ONC_1426	Pepaxto (melphalan flufenamide)	Negative change	Remove inclusion criteria: Multiple Myeloma. 1.Pepaxto is recommended for members with relapsed/refractory multiple myeloma for 5th line (fifth-line) therapy. Members must have received prior therapy and experienced disease progression on 4 or more lines of therapy including: one or more proteasome inhibitors, one or more immunomodulatory agents, and one anti CD-38 antibody. 2.NOTE: Based on the HORIZON trial, febrile neutropenia was 5% and primary prophylaxis with a G-CSF is not required.	Not recommended per FDA safety alert