Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
NEW	Abecma (idecabtagene vicleucel)	N/A	N/A	N/A
UM ONC_1041	LHRH agonists and antagonist	N/A	N/A	N/A- Add addendum for Fidelis Care state specific criteria
UM ONC_1179	Abraxane (nab-paclitaxel)	Negative change	Add inclusion criteria: 3. Breast cancer- Abraxane (nab-paclitaxel) may be used in combination with Tecentriq (atezolizumab) in the first line setting OR in the second line/subsequent line setting if the member has not received the above regimen previously and there is no history of progression on another Immune Checkpoint Inhibitor (e.g. Keytruda) 5.Non-Small Cell Lung Cancer (NSCLC) a.In the first line setting for metastatic, squamous, Non-Small Cell Lung Cancer, Taxol (paclitaxel) is preferred over Abraxane (nab-paclitaxel). The above recommendation is based on results of KEYNOTE-407 trial which showed no difference in outcomes between the use of Taxol (paclitaxel) and Abraxane (nab-paclitaxel).	Per Clinical Trial Analysis/Criteria
UM ONC_1179	Abraxane (nab-paclitaxel)	Positive change	Remove exclusion criteria: 1.Off-label indications for Abraxane (nab-paclitaxel) in ovarian cancer, metastatic melanoma, urothelial carcinoma, and endometrial carcinoma.	Per Clinical Trial Analysis/Criteria
UM ONC_1195	Votrient (pazopanib)	Positive change	Remove inclusion criteria: Advanced/Metastatic Renal Cell Carcinoma c.NOTE: Votrient (pazopanib) is PREFERRED in subsequent setting for any IMDC risk clear cell RCC per NCH pathway & NCH Policy (if not used in first line).	Per NCH L1 Pathway
UM ONC_1196	Sprycel (dasatinib)	Positive change	Remove inclusion criteria: 2.Chronic Myeloid Leukemia (CML)- b. c.As initial or subsequent therapy for members with CML with any of the following mutations: Y253H or E255K/V.	Per Compendia Listing
UM ONC_1196	Sprycel (dasatinib)	Negative change	Add exclusion criteria: 2.Sprycel (dasatinib) is being used on Ph or BCR-ABL negative CML or in members with the following mutations of BCR-ABL1: T315I/A, F317L/V/I/C or V299L. .	Per Compendia Listing
UM ONC_1200	Torisel (temsrolimus)	Negative change	Add inclusion criteria: 2.Renal Cell Carcinoma (RCC) a.NOTE: Per NCH Policy & NCH Pathway, Torisel is only recommended as monotherapy for metastatic clear cell renal cell carcinoma, in members who have failed two oral TKIs and one or more Immune Checkpoint Inhibitor..	Step Therapy Criteria
UM ONC_1200	Torisel (temsrolimus)	Positive change	Remove inclusion criteria: b.Torisel (temsirolimus) may be used as a single agent for initial/subsequent therapy in members with metastatic/advanced non-clear cell Renal Cell Carcinoma-RCC.	More Cost Effective Alternative(s)
UM ONC_1207	Zelboraf (vemurafenib)	Negative change	Add inclusion criteria: B.Malignant Melanoma 2.NOTE: Per NCH Policy & NCH Pathway, Zelboraf (vemurafenib) in combination with a MEK inhibitor (e.g. cobimetinib) is a non-preferred regimen/combination for use as adjuvant therapy in resected stage III melanoma; Opdivo (nivolumab) or Keytruda(pembrolizumab) for 1 year is the preferred option in this clinical setting. This recommendation is based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) supporting superior outcomes with anti-BRAF targeted therapy vs Immune Checkpoint Inhibitor therapy. 3.NOTE: Per NCH Pathway & NCH Policy, Zelboraf (vemurafenib) in combination with Cotellic (cobimetinib) + Tecentriq (atezolizumab) is non-preferred for the treatment of metastatic/recurrent/unresectable BRAF V600 mutation positive malignant melanoma.This recommendation is based on the lack of Level 1 evidence (randomized trials and or meta-analyses) supporting superior outcomes with the above regimen in comparison to [Yervoy(ipilimumab) + Opdivo(nivolumab)] the recommended regimen per NCH policy.	Per Clinical Trial Analysis/Criteria
UM ONC_1207	Zelboraf (vemurafenib)	Positive change	Add exclusion criteria: B.Use of Zelboraf (vemurafenib) ~~as a single agent~~ or in combination with Cotellic (cobimetinib) + Tecentriq (atezolizumab) in metastatic/recurrent/unresectable BRAF V600 mutation positive malignant melanoma. D.Treatment exceeds the maximum limit of 240 (240 mg) ~~capsules~~ tablets a month.	per FDA Labeling
UM ONC_1226	Zaltrap (ziv-aflibercept)	Negative change	Add inclusion criteria: Zaltrap use is not recommended for metastatic colorectal cancer.	More Cost Effective Alternative(s)
UM ONC_1240	Synribo (omacetaxine)	Negative change	Add inclusion criteria: 2.Chronic Myelogenous Leukemia i.The member has experienced disease progression / intolerance to three or more of the following tyrosine kinase inhibitors: Gleevec (imatinib), Tasigna (nilotinib), or Bosulif (bosutinib), or Sprycel(dasatinib) OR ii.The member has a T315I mutation and has failed Iclusig (ponatinib) to treat CML with this mutation.	Step Therapy Criteria
UM ONC_1250	Tafinlar (dabrafenib)	Negative change	Add inclusion criteria: 2.BRAF V600E or V600K mutation positive Melanoma a.NOTE: For adjuvant therapy of BRAF V600 E or V600K mutation positive, stage III melanoma, the preferred agents per NCH Policies & NCH Pathway, for adjuvant therapy 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.	Per NCH L1 Pathway
UM ONC_1250	Tafinlar (dabrafenib)	Positive change	Add inclusion criteria: b.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. c.Tafinlar (dabrafenib) may be used as a single agent or in combination with Mekinist (trametinib) in members who have intolerance to/contraindication to the use of [Cobimetinib + Vemurafenib].	Per Compendia Listing

Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
UM ONC_1250	Tafinlar (dabrafenib)	Negative change	Remove inclusion criteria: 3.Non-Small Cell Lung Cancer (NSCLC) a.Tafinlar (dabrafenib) may be used ~~as a single agent or~~ in combination with Mekinist (trametinib) as first line or subsequent line therapy for recurrent or metastatic BRAF V600E mutation-positive NSCLC. 4.Thyroid Cancer a.The member has anaplastic, papillary, follicular, and Hürthle Cell thyroid carcinoma and Tafinlar (dabrafenib) may be used ~~as a single agent/~~in combination with Mekinist (trametinib) for radioactive iodine-refractory (if radioactive iodine therapy is appropriate) BRAF V600E mutation-positive unresectable/recurrent/metastatic disease.	Per Compendia Listing
UM ONC_1250	Tafinlar (dabrafenib)	Positive change	Add inclusion criteria: 4.Thyroid Cancer a.The member has anaplastic, papillary, follicular, and Hürthle Cell thyroid carcinoma and Tafinlar (dabrafenib) may be used as a single agent/in combination with Mekinist (trametinib) for radioactive iodine-refractory (if radioactive iodine therapy is appropriate) BRAF V600E mutation-positive unresectable/recurrent/metastatic disease.	Per Compendia Listing
UM ONC_1271	Farydak (panobinostat)	Negative change	Add inclusion criteria: 2.Multiple Myeloma NOTE: PANOBINOSTAT containing regimens are NON-PREFERRED for use in relapsed/refractory multiple myeloma. a.Farydak(panabinostat) is not recommended for use in relapsed/refractory multiple myeloma. Alternative options are available, please refer to NCH L1 pathway for multiple myeloma.	More Cost Effective Alternative(s)
UM ONC_1271	Farydak (panobinostat)	Negative change	Remove inclusion criteria: b.The member has relapsed/refractory multiple myeloma and Farydak (panobinostat) may be used as the following: i.In combination with bortezomib and dexamethasone AND ii.The member received at least 1-3 prior therapies including bortezomib and an immunodulatory agent (i.e. thalidomide, lenalidomide, or pomalidomide).	More Cost Effective Alternative(s)
UM ONC_1271	Farydak (panobinostat)	Positive change	Remove exclusion criteria: A 1.Disease progression while taking Farydak (panobinostat). 2.Dosing exceeds single dose limit of Farydak (panobinostat) 20 mg. 3.Treatment exceeds the maximum duration limit of 16 treatment cycles. 4.Treatment exceeds the maximum limit of 6 (20mg) capsules/month, 12 (10 mg) capsules/month, or 6 (15 mg) capsules/month.	More Cost Effective Alternative(s)
UM ONC_1271	Farydak (panobinostat)	Negative change	Add exclusion criteria: Farydak(panabinostat) is not recommended for use in myeloma.	More Cost Effective Alternative(s)
UM ONC_1272	Ibrance (palbociclib)	Negative change	Add inclusion criteria: Ibrance (Palbociclib) may be used in members with ER/PR positive and HER2 negative recurrent or metastatic breast cancer and the member has intolerance/contraindication to Kisqali (ribociclib).	Per Compendia Listing
UM ONC_1273	Lynparza (olaparib)	Negative change	Add inclusion criteria: 2. Ovarian Cancer NOTE: The Preferred PARP inhibitor, per NCH Policies and NCH Pathways, for maintenance therapy-either first line or after a platinum-sensitive relapse-in ovarian cancer is Zejula (niraparib). This recommendation is based on a lack of level 1 evidence (randomized trials and/or meta-analyses) demonstrating superiority of Lynparza (olaparib) over Zejula (niraparib).	Per NCH L1 Pathway
UM ONC_1273	Lynparza (olaparib)	Positive change	Add inclusion criteria: 5.Prostate Cancer NOTE: Lynparza (Olaparib) is only recommended in metastatic castration-resistant prostate cancer with mutations in DNA repair genes including but not limited to germline/somatic BRCA1 or BRCA2 deleterious/suspected deleterious mutations. a.The member has metastatic castration-resistant prostate Cancer AND b.Tumor is positive for germline or somatic BRCA 1/2 or other DNA Repair gene mutation/genomic aberration, as confirmed on a CLIA approved diagnostic test (e.g. Foundation One CDx or BRAC Analysis CDx)	Per Compendia Listing
UM ONC_1273	Lynparza (olaparib)	Negative change	Remove exclusion criteria: 3.Dosing exceeds single dose limit of Lynparza (olaparib) ~~400 mg (capsule) or~~ 300 mg (tablet). 4.Treatment exceeds the maximum limit of ~~480 (50 mg) capsules/180~~60 (100 mg) and 120 (150 mg) tablets per month.	Per FDA Labeling

Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
UM ONC_1274	Opdivo (nivolumab)	Negative change	Add inclusion criteria: D.Renal Cell Carcinoma c.NOTE: [Opdivo (nivolumab)+ Cabometyx (cabozantinib)] is a non-preferred regimen per NCH Policy. This rationale for this position is as follows : i.This regimen has not been shown to be superior to the NCH preferred regimen of [Yervoy (ipilimumab) + Opdivo (nivolumab) in a randomized trial. ii.This regimen did not show an OS benefit vs Sutent (sunitinib) in the IMDC Favorable Risk category in the CheckMate 9ER trial. E.Hodgkin's Lymphoma NOTE: The preferred Immune Checkpoint Inhibitor, for members with relapsed/refractory Hodgkin's Lymphoma (including members who failed or are not candidates for autologous stem cell transplant) is Keytruda (pembrolizumab). 1.Opdivo may be used in a member with The member has classical Hodgkin's Lymphoma that has relapsed or progressed after autologous hematopoietic stem cell transplantation (HSCT) AND post-transplantation +/- Adcetris (brentuximab vedotin) OR has progressed after 3 or more prior lines of systemic therapy, and the member has not received prior therapy with an Immune Checkpoint Inhibitor AND 2.NOTE: Opdivo (nivolumab) given in combination with Adcetris (brentuximab vedotin) is a Non-Preferred regimen per NCH Policy. This recommendation is based on the lack of Level 1 evidence (randomized clinical trial and/or meta-analyses) to support superior outcomes with the above combination compared to either single agent Opdivo (nivolumab) or single agent Adcetris (brentuximab). H.Colorectal Cancer NOTE: For metastatic MSI-High colorectal cancer, the preferred Checkpoint Inhibitor is Keytruda (pembrolizumab).	Per Clinical Trial Analysis/Criteria
UM ONC_1297	Venclexta (venetoclax)	Positive change	Remove inclusion criteria: 2. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) a.NOTE #1: Please refer to the NCH Pathway document for the latest recommended regimens for CLL. 3. AML - Remission induction therapy & post-remission therapy for members with unfavorable-risk cytogenetics/members unsuitable for intensive remission induction therapy/members who decline intensive therapy. 4.Mantle Cell Lymphoma a.NOTE: Please refer to the NCH Pathway document for the latest recommended treatment options for Mantle Cell Lymphoma.	Per Clinical Trial Analysis/Criteria
UM ONC_1297	Venclexta (venetoclax)	Negative change	Add inclusion criteria: b.NOTE #2: Please note that per NCH Policy & NCH Pathway, the combination of Venclexta (venetoclax) and Gazyva (obinutuzumab) for first line therapy of CLL/SLL is a Non-Preferred Regimen. This recommendation is based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) to show superior outcomes with the above combination when compared with Venclexta (venetoclax) and Rituximab biosimilars. 3.Acute Myeloid Leukemia (AML) a. Venclexta (venetoclax) may be used in combination with either decitabine or azacitidine for members with AML who have unfavorable-risk cytogenetics or are unsuitable for intensive remission induction therapy or decline intensive therapy; either of the above combinations may be used.	Per Clinical Trial Analysis/Criteria
UM ONC_1297	Venclexta (venetoclax)	Positive change	Remove exclusion criteria: 4.Treatment exceeds the maximum limit of ~~120~~180 (100 mg) or 240 (50 mg) tablets per month.	Per FDA Labeling
UM ONC_1301	Rubraca (rucaparib)	Negative change	Add inclusion criteria: 2.Ovarian Cancer a.NOTE: Rucaparib is a non-preferred PARP-inhibitor per NCH Policy for ovarian cancer. The preferred PARP inhibitor is Niraparib.	More Cost Effective Alternative(s)
UM ONC_1301	Rubraca (rucaparib)	Negative change	Add exclusion criteria: 5.Treatment exceeds the maximum limit of 120 (300 mg), 120 (250 mg), ~~tablets/month~~ or 180 (200 mg) tablets/month.	per FDA Labeling
UM ONC_1307	Zejula (niraparib)	Negative change	Add inclusion criteria: 2.Ovarian Cancer a.Niraparib monotherapy may be used in ANY one of the following: i.The member has newly diagnosed stage III/IV ovarian carcinoma and has undergone surgery (with or without optimal debulking) and has completed first line platinum-based chemotherapy AND Niraparib is being used as a single agent for maintenance therapy (regardless of BRCA mutation test results). NOTE: Niraparib is the Preferred agent per NCH Policy & NCH Pathway in this setting.This recommendation is based on the lack of Level 1 evidence (randomized clinical trial and or meta-analyses) to support the superiority of other maintenance regimens, specifically olaparib and [olaparib+bevacizumab] over niraparib alone.	Per Clinical Trial Analysis/Criteria
UM ONC_1307	Zejula (niraparib)	Negative change	Add exclusion criteria: 2.Concurrent use with other anti-cancer therapy including bevacizumab.	Per Clinical Trial Analysis/Criteria
UM ONC_1324	Kymriah (tisagenlecleucel)	Negative change	Add inclusion criteria: B-Cell Lymphomas - 2.Members must have previously received at least two lines of therapy, including rituximab and an anthracycline (for DBCL)	Per Clinical Trial Analysis/Criteria

Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
UM ONC_1324	Kymriah (tisagenlecleucel)	Negative change	Add exclusion criteria: Member does not have adequate bone marrow reserve defined by ALL of the following: 1.Absolute neutrophil count (ANC) ≥ 1000/uL; and 2.Absolute lymphocyte count (ALC) > 300/uL; and 3.Platelet Count ≥ 50,000/uL C.Member does not have adequate renal, hepatic, cardiac and pulmonary function defined as: 1.Creatinine clearance ≥ 60 mL/min 2.Serum ALT ≤5 times the upper limit of normal 3.Cardiac ejection fraction ≥ 45%, no evidence of pericardial effusion as determined by an echocardiogram (ECHO), and no clinically significant pleural effusion 4.Baseline oxygen saturation > 91% on room air. D. History of seizures or other CNS disorder E. History of autoimmune disease B.F.Active serious infection.	Per Clinical Trial Analysis/Criteria
UM ONC_1327	Aliqopa (copanlisib)	Negative change	Add inclusion criteria: B.Indolent B Cell NHL (Follicular B Cell Lymphoma grades 1-3a, Marginal Zone Lymphoma, Small Lymphocytic Lymphoma with an absolute lymphocyte count < 5 x 109, lymphoplasmacytic lymphoma/Waldenstrom's Macroglobulinemia[with IgM paraprotein or >10% of lymphoplasmacytic cells in the bone marrow] 1. NOTE: Per NCH Pathway & NCH Policy Aliqopa (copanlisib) is a Non-Preferred agent in any setting for the treatment of Follicular B-cell lymphoma, Marginal Zone Lymphoma & SLL. This recommendation is based on the fact that the ONLY endpoint for the CHRONOS-1 trial -that led to the FDA approval of this drug- was ORR- Overall Response Rate.	Per Clinical Trial Analysis/Criteria
UM ONC_1327	Aliqopa (copanlisib)	Negative change	Add exclusion criteria: Not recommended	More Cost Effective Alternative(s)
UM ONC_1327	Aliqopa (copanlisib)	Positive change	Remove exclusion criteria: A.Aliqopa (copanlisib) is being used after disease progression with the same regimen or prior PI3K inhibitors [e.g. Zydelig (idelalisib) or Copiktra (duvelisib)]. B.Concurrent use with other chemotherapy, immunotherapy, or ongoing systemic corticosteroid. C.Dosing exceeds single dose limit of Aliqopa (copanlisib) 60 mg.	More Cost Effective Alternative(s)
UM ONC_1329	Yescarta (axicabtagene ciloleucel)	Positive change	Add inclusion criteria: 2.The member has chemotherapy-refractory disease, defined as one or more of after the following: a. ~~No response to last line of therapy~~Two or more lines of systemic chemotherapy OR b.For DLBCL, two or more lines of systemic chemotherapy, including rituximab and an anthracycline. ~~Disease progression or relapse less ≤12 months after autologous stem cell transplantation (ASCT).~~	Per Clinical Trial Analysis/Criteria
UM ONC_1329	Yescarta (axicabtagene ciloleucel)	Negative change	Add exclusion criteria: E.The member does not have adequate bone marrow reserve defined by ALL of the following: 1.Absolute neutrophil count (ANC) ≥ 1000/uL 2.Absolute lymphocyte count (ALC) ≥ 100/uL 3.Platelet Count ≥ 75,000/uL. F.The member does not have adequate renal, hepatic, cardiac and pulmonary function defined as: 1.Creatinine clearance ≥ 60 mL/min 2.Serum ALT/AST <2.5 times the upper limit of normal 3.Total bilirubin <1.5 mg/dl, except in subjects with Gilbert's syndrome 4.Cardiac ejection fraction ≥ 50%, no evidence of pericardial effusion as determined by an echocardiogram (ECHO), and no clinically significant pleural effusion 5.Baseline oxygen saturation > 92% on room air. G.Primary central nervous system lymphoma H.Active central nervous system malignancy I.History of seizures or other CNS disorder J.History of autoimmune disease K.Prior Allogeneic hematopoietic stem cell transplant (HSCT) L.Active serious infection	Per Clinical Trial Analysis/Criteria
UM ONC_1335	Braftovi (encorafenib)	Negative change	Add inclusion criteria: B.Melanoma 1.NOTE: The preferred BRAF and MEK inhibitor combination regimen, per NCH policy and pathway, for unresectable/metastatic BRAF mutation positive melanoma is the combination of Cotellic (cobimetinib) + Zelboraf (vemurafenib) over Mektovi (binimetinib) + Braftovi (encorafenib). This recommendation is based on the lack of Level 1 evidence (randomized trials and or meta-analyses) showing the superiority of Braftovi (encorafenib) + Mektovi (binimetinib) over the preferred regimen. 1.Braftovi (encorafenib) may be used in BRAFV600E or V600K mutation positive unresectable/metastatic melanoma in members who have intolerance/contraindication to Zelboraf (vemurafenib) + Cotellic (cobimetinib). C.Metastatic Colorectal Cancer 2.Braftovi (encorafenib) will be used in combination with Erbitux (cetuximab) or Vectibix (panitumumab) after prior therapy with an oxaliplatin and/or irinotecan containing regimen.	Per Clinical Trial Analysis/Criteria

Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
UM ONC_1346	Copiktra (duvelisib)	Negative change	Add inclusion criteria: B.Indolent Non Hodgkin's Lymphoma (Follicular Non-Hodgkin Lymphoma (NHL), Marginal Zone Lymphoma) 1.Copiktra(duvelisib) may be used as monotherapy for members with relapsed Indolent NHL who have experienced disease progression on or after 2 prior lines of therapy (prior therapies must have included any 2 of the following: rituximab monotherapy/rituximab+chemotherapy/RIT-Radio Immuno Therapy e.g. Zevalin). hronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (CLL/SLL) CLL/SLL 2.Copiktra (duvelisib) will be used as a single agent following disease progression on at least two prior therapies, including bendamustine + rituximab Treanda (bendamustine) + Rituxan (rituximab) and ibrutinib (unless there is intolerance/contraindication to ibrutinib). The latter recommendation is based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) to show the superiority of duvelisib over either BR or ibrutinib.	Per Clinical Trial Analysis/Criteria
UM ONC_1346	Copiktra (duvelisib)	Negative change	Add exclusion criteria: C.Treatment exceeds the maximum limit of 60 (25 mg) or 60 (15 mg) tablets/month.	Per FDA Labeling
UM ONC_1360	Piqray (alpelisib)	Negative change	Add inclusion criteria: Breast cancer iv.Member has experienced disease progression on or after therapy with an aromatase inhibitor + a CDK4/6 inhibitor (e.g., abemaciclib, palbociclib, or ribociclib).	Step Therapy Criteria
UM ONC_1360	Piqray (alpelisib)	Negative change	Add exclusion criteria: 2.Previous Fulvestrant therapy 3.Previous therapy with an mTOR inhibitor e.g. everolimus 6. Treatment exceeds the maximum limit of 60 (150 mg), 60 (100 mg), or 120 (50 mg) tablets/month.	Per Clinical Trial Analysis/Criteria
UM ONC_1360	Piqray (alpelisib)	Positive change	Remove exclusion criteria: Receipt of previous chemotherapy for advanced/metastatic disease	
UM ONC_1365	Xpovio (selinexor)	Negative change	Add inclusion criteria: B.Multiple Myeloma NOTE: Xpovio is a Non-Preferred drug for use in Multiple Myeloma per the NCH Policy. Several other alternative treatment options are available. 1.Xpovio (selinexor) may be used as a single agent for a member with relapsed/refractory multiple myeloma who has experienced disease progression on at least 4 prior lines of therapy including two ~~one~~ proteasome inhibitor (e.g. bortezomib, carfilzomib, ixazomib), two~~one~~ immunomodulatory agent (e.g. lenalidomide, thalidomide, pomalidomide), and Darzalex (daratumumab). C.Diffuse Large B-cell Lymphoma (DLBCL) NOTE: Xpovio is a Non-Preferred drug per NCH Policy, for relapsed/refractory Diffuse Large B-Cell Lymphoma (and all related Large B-Cell Lymphomas)	Step Therapy Criteria
UM ONC_1365	Xpovio (selinexor)	Negative change	Add exclusion criteria: D.Treatment exceeds the maximum limit of 8 (40, 60mg, or 80 mg) ~~, 8 (80mg),~~ or 4 (100mg) tablets/month.	Per FDA Labeling
UM ONC_1413	Tecartus (brexucabtagene autoleucel)	Negative change	Add inclusion criteria: B.Mantle Cell Lymphoma, CD-19 positive Tecartus (brexucabtagene autoleucel) may be used as monotherapy will be used in members 18 years or older with relapsed/refractory Mantle Cell Lymphoma ~~that has progressed that~~ on ~~2 prior therapieswas either relapsed or refractory to up to~~ 5 prior regimens. Prior therapy should have includedincluding a chemo-immunotherapy regimen (e.g.e.g., R-CHOP, or BR, R-HyperCVAD) and a BTK (Bruton Tyrosine Kinase) inhibitor (e.g. ibrutinib, acalabrutinib, or zanubrutinib). Member should have a confirmed diagnosis of Mantle Cell Lymphoma, either with cyclinD1 overexpression or a positive t(11;14) translocation in the lymphoma cells.	Per Clinical Trial Analysis/Criteria
UM ONC_1413	Tecartus (brexucabtagene autoleucel)	Negative change	Add exclusion criteria: B.CD-19 positivity not confirmed. C.Diagnosis of Mantle Cell Lymphoma not confirmed by either a positive cyclin D1 expression or a positive t(11;14) translocation in lymphoma cells. A.D.The member does not have adequate bone marrow reserve defined by ALL the following: 1.Absolute neutrophil count (ANC) ≥ 1000 cells/uL 2.Absolute lymphocyte count (ALC) ≥ 100 cells/uL 3.Platelet Count ≥ 75,000/uL. B.E.The member does not have adequate renal, cardiac, and pulmonary function defined as: 1.Creatinine clearance ≥ 60 mL/min 2.Cardiac ejection fraction ≥ 50% and there is no evidence of pericardial effusion as determined by an echocardiogram (ECHO) 3.EKG has no clinically significant findings 4.Baseline oxygen saturation >92% on room air. C.F.Prior Allogeneic hematopoietic stem cell transplant (HSCT) D.G.History of CNS lymphoma (including lymphomatous meningitis), history of brain metastases, or any CNS disorder E.H.Active serious infection I.Does not exceed duration limit as one time administration.	Per Clinical Trial Analysis/Criteria
UM ONC_1420	Margenza (margetuximab-cmkb)	Negative change	Add inclusion criteria: B.Metastatic HER-2 + Breast Cancer NOTE: Margenza(margetuximab) is a Non-Preferred drug per NCH Policy based on a lack of level 1 evidence demonstrating superiority over trastuzumab containing regimens.	More Cost Effective Alternative

Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
UM ONC_1421	Breyanzi (lisocabtagene maraleucel)	Negative change	Add inclusion criteria: B.Diffuse Large B-Cell Lymphoma, confirmed CD-19 positive 1.Breyanzi (lisocabtagene maraleucel) may be used, as monotherapy, for the treatment of adult members with relapsed or refractory large B-cell lymphoma (CD-19 positive) after disease progression on/after two or more lines of systemic therapy , including chemoimmunotherapy containing anti-CD20 and anthracycline (unless anthracyclines are contraindicated) ~~and/or and/or hematopoietic stem cell transplant.~~	Per FDA Labeling
UM ONC_1421	Breyanzi (lisocabtagene maraleucel)	Negative change	Add exclusion criteria: C.Does not exceed duration limit as one time administration. D.The member does not have adequate bone marrow reserve. E.The member does not have adequate renal, hepatic, cardiac and pulmonary function defined as: 1.Creatinine clearance > 30 mL/min 2.Serum ALT ≤5 times the upper limit of normal 3.Cardiac ejection fraction ≥ 40%, no evidence of pericardial effusion as determined by an echocardiogram (ECHO), and no clinically significant pleural effusion 4.Baseline oxygen saturation > 91% on room air. F.Primary central nervous system lymphoma. G.Active serious infection. H.Inflammatory disorders.	Per Clinical Trial Analysis/Criteria