

Policy	Drug(s)	Type of Change	Brief Description of Policy Change
new policy	Elitek (rasburicase)	n/a	n/a
new policy	Retevmo (selpercatinib)	n/a	n/a
new policy	Tabrecta (capmatinib)	n/a	n/a
new policy	Trodelvy (govitecan-hziy)	n/a	n/a
new policy	Qinlock (ripretinib)	n/a	n/a
UM ONC_1048	Campath (alemtuzumab)	Archive	<p>Campath is no longer being used for any Hematology Oncology indications.</p> <p>Remove inclusion criteria:</p> <p>ALL: Induction, consolidation, maintenance, relapsed/refractory combination removed and use is supported as a part of a multi-agent chemotherapy regimen, for all sub-types of ALL, for induction/consolidation therapy, and for therapy of relapsed refractory disease</p> <p>NHL: Induction, consolidation, maintenance, relapsed/refractory combination removed and use is supported for extra-nodal NK/T-cell lymphoma (nasal type) and as a part of a multi-agent chemotherapy regimen for either first line therapy and/or therapy for relapsed /refractory disease.</p>
UM ONC_1063	Oncaspar (pegaspargase)	Positive change	Remove exclusion criteria: History of serious thrombosis, pancreatitis, or hemorrhagic events with L-asparaginase (ELSPAR) therapy.
UM ONC_1064	Oncaspar (pegaspargase)	Positive change	
UM ONC_1134	Trastuzumab products	Negative change	<p>Add exclusion criteria: Dosing exceeds single dose limit of Trastuzumab 8 mg/kg for the loading dose, 6 mg/kg for subsequent doses when given every 3 weeks; 4 mg/kg for the loading dose and 2 mg/kg for the weekly dose.</p> <p>Remove exclusion criteria: Velcade (bortezomib) is being used after disease progression on another Velcade-based regimen.</p>
UM ONC_1136	Velcade (bortezomib)	Positive change	<p>Add inclusion criteria:</p> <p>Multiple Myeloma:</p> <p>- NOTE: The preferred agent, per NCH policy, is generic bortezomib over brand bortezomib (Velcade) for all indications, unless there are contraindications or intolerance to generic bortezomib.</p>
UM ONC_1136	Velcade (bortezomib)	Negative change	Add inclusion criteria: Use is supported if there is a history of a severe allergic reaction/anaphylaxis to solvent-based paclitaxel (Taxol) or docetaxel
UM ONC_1179	Abraxane (nab-paclitaxel)	Negative change	Breast cancer: CPS- Combined Positive Score in the tumor tissue is 1% or higher
UM ONC_1179	Abraxane (nab-paclitaxel)	Negative change	<p>Add exclusion criteria: Disease progression while receiving Abraxane or an Abraxane containing regimen</p> <p>Remove exclusion criteria: 1. Off-label indications for Abraxane (nab-paclitaxel) in neoadjuvant treatment of pancreatic adenocarcinoma,</p>
UM ONC_1179	Abraxane (nab-paclitaxel)	Positive change	
UM ONC_1179	Abraxane (nab-paclitaxel)	Positive change	Add inclusion criteria: Used in combination with gemcitabine for neoadjuvant therapy for borderline resectable or locally advanced pancreatic adenocarcinoma

			<p>Add inclusion criteria: RCC- NOTE: The preferred tyrosine kinase inhibitor, per NCH Policy & NCH Pathway for first line advanced/metastatic clear cell renal cell carcinoma, IMDC Good Risk (Favorable Risk) Disease, is Votrient(pazopanib) NOTE: Votrient (pazopanib) is preferred in subsequent setting for any IMDC risk clear cell RCC per NCH pathway (if not used in first line)</p>
UM ONC_1195	Votrient (pazopanib)	Negative change	<p>Add inclusion criteria: a. Pazopanib use is supported as a single agent, for first line therapy of recurrent/metastatic renal cell carcinoma (predominantly clear cell histology) AND IMDC Criteria Favorable Risk Disease b. Pazopanib use is supported as a single agent, for subsequent line therapy for recurrent/metastatic renal cell carcinoma (predominantly clear cell histology) regardless of IMDC Risk Category, if the member has not received prior therapy with an oral Multi Kinase Inhibitor (e.g. Sunitinib, Axitinib, Cabozantinib) c. Pazopanib use is supported, as a single agent, for First line/ Subsequent line therapy for metastatic/recurrent renal cell carcinoma of predominantly Non-Clear cell histology</p>
UM ONC_1195	Votrient (pazopanib)	Positive change	<p>Remove inclusion criteria: a. as a single agent, soft tissue sarcoma of the extremity/trunk or retroperitoneal/intraabdominal origins b. Have failed 2 combination chemotherapy regimens including an anthracycline based therapy except if medically contraindicated OR c. Treatment for progressive disease when member is no longer receiving benefit from imatinib, sunitinib, or regorafenib for Gastrointestinal Stromal Tumors (GIST).</p>
UM ONC_1195	Votrient (pazopanib)	Positive change	
UM ONC_1195	Votrient (pazopanib)	Positive change	Add inclusion criteria: a. Sarcoma - as a single agent
UM ONC_1195	Votrient (pazopanib)	Positive change	Remove exclusion criteria: 2. The member has severe hepatic impairment (total bilirubin greater than 3 times ULN).
UM ONC_1196	Sprycel (dasatinib)	Negative change	Add exclusion criteria:- Use in members with the following BCR-ABL1 mutations: T315I/A, F317L/V/I/C or V299L
			<p>Add inclusion criteria: NOTE: Per NCH Policy & NCH Pathway, generic Imatinib is the preferred agent for first line therapy of BCR-ABL positive Chronic Myeloid Leukemia. Second generation TKIs- Tyrosine Kinase Inhibitors- such as Sprycel (dasatinib) may be used if there is documented intolerance to generic Imatinib, OR, documented disease progression on generic Imatinib. Acute Lymphoblastic Leukemia (ALL)</p>
UM ONC_1196	Sprycel (dasatinib)	Negative change	a. The member has Ph Positive ALL with resistance or intolerance to prior therapy, including Gleevec (imatinib).

			<p>Remove inclusion criteria: Chronic Myeloid Leukemia (CML) a. Primary treatment for members with newly diagnosed CML (PH-1+ or BCR-ABL positive) OR b. Follow-up therapy, after Gleevec (imatinib) or Tasigna (nilotinib) primary treatment. c. Treatment of members with advanced phase CML i. As a single agent for accelerated phase ii. As a single agent or in combination with induction chemotherapy followed by hematopoietic stem cell transplant for blast crisis. d. Post-transplant follow-up treatment in members with i. Molecular relapse (polymerase chain reaction positive) following complete cytogenetic remission ii. Cytogenetic relapse or those who are not in cytogenetic remission. e. As follow up therapy for F359V/C/I mutation</p>
UM ONC_1196	Sprycel (dasatinib)	Positive change	
UM ONC_1196	Sprycel (dasatinib)	Positive change	<p>Add inclusion criteria: CML a. As a single agent fPrimary treatment for members with newly diagnosed CML (PhH-1+ or BCR-ABL positive) who are intolerant to generic Imatinib, or have experienced disease progression on generic Imatinib.OR a.b.As initial or subsequent therapy for members with CML with any of the following mutations: Y253H or E255K/V</p>
UM ONC_1196	Sprycel (dasatinib)	Negative change	<p>Add exclusion criteria: 1. Member has not had a trial of generic Imatinib for first line therapy of BCR/ABL+ or Philadelphia Chromosome + CML</p>
UM ONC_1200	Torisel (temsirolimus)	Negative change	<p>Add inclusion criteria: NOTE: Per NCH Policy & NCH Pathway, Torisel is NOT a recommended agent for use in renal cell carcinoma. Please refer to the NCH Pathway document to see the most current recommended regimens/agents for Renal Cell Carcinoma</p>
UM ONC_1200	Torisel (temsirolimus)	Positive change	<p>Remove inclusion criteria: Renal Cell Carcinoma (RCC) a. First-line or subsequent therapy as a single agent for relapsed or medically unresectable stage IV clear cell histology disease AND with ≥ 3 high risk features: i. Serum lactate dehydrogenase level (LDH) > 1.5 times the upper limit of normal ii. Hemoglobin level below normal iii. Corrected serum calcium > 10 milligrams/deciliter (mg/dL) iv. Interval of less than a year from initial diagnosis v. Karnofsky performance status of 60 or 70 (for ECOG conversion status, please see appendix A). vi. 2 or greater metastatic sites.</p>
UM ONC_1200	Torisel (temsirolimus)	Negative change	<p>Add exclusion criteria: - Concurrent use with other chemotherapy, immunotherapy, or targeted therapy.</p>
UM ONC_1200	Torisel (temsirolimus)	Positive change	<p>Remove exclusion criteria: 1. The member has moderate to severe liver disease, bilirubin greater than 1.5 x ULN. 2. Torisel (temsirolimus) is being used without pretreatment medications (i.e. diphenhydramine).</p>

UM ONC_1201	Yervoy (ipilimumab)	Negative change	<p>Add inclusion criteria: 8. Non-Small Cell Lung Cancer NOTE: The combination of [Yervoy(ipilimumab + Opdivo(nivolumab))] for metastatic Non-Small Cell Lung Cancer, in the first line/subsequent line setting, is a Non-Preferred combination per NCH Policy and NCH Pathway. Please refer to the NCH Pathway document for the most current recommended regimens/agent for metastatic Non- Small Cell Lung Cancer.</p>
UM ONC_1207	Zelboraf (vemurafenib)	Negative change	<p>Add inclusion criteria: NOTE: Per NCH Policy & NCH Pathway, Vemurafenib +Cobimetinib is the preferred combination therapy for BRAF V600 E positive melanoma, both in the first line and subsequent line settings.</p>
UM ONC_1207	Zelboraf (vemurafenib)	Positive change	<p>Remove inclusion criteria: 1. Malignant Melanoma a. Zelboraf (vemurafenib) is being used as a single agent for recurrent malignant melanoma iii. Reinduction therapy for members with performance status 0-2 who experience disease control and have no residual toxicity, but subsequently experience disease progression/relapse >3 months after treatment discontinuation.</p>
UM ONC_1207	Zelboraf (vemurafenib)	Negative change	<p>Add inclusion criteria: 1. Malignant Melanoma ii. Second-line or subsequent line therapy if the member has not been treated previously with vemurafenib + cobimetinib or other BRAF inhibitor + MEK inhibitor combinations</p>
UM ONC_1207	Zelboraf (vemurafenib)	Negative change	<p>Add inclusion criteria: 1. Malignant Melanoma ii. Second-line or subsequent line therapy if the member has not been treated previously with vemurafenib + cobimetinib or other BRAF inhibitor + MEK inhibitor combinations</p>
UM ONC_1207	Zelboraf (vemurafenib)	Negative change	<p>Add exclusion criteria: 2. Zelboraf(vemurafenib) is being used as a single agent in metastatic/recurrent/unresectable BRAFV600E + malignant melanoma</p>
UM ONC_1226	Zaltrap (ziv-aflibercept)	Negative change	<p>Add inclusion criteria: 1. NOTE: Per NCH Policy & NCH Pathway Zaltrap (ziv-aflibercept) is a NON-PREFERRED drug for metastatic colorectal cancer. Please refer to the NCH Pathway document to see the most current recommended regimens/agents for colorectal cancer. 2. NOTE: Unless contraindications/intolerance exist, Bevacizumab containing regimens are preferred over Zaltrap or Cyramza containing regimens for members with metastatic CRC.</p>
UM ONC_1226	Zaltrap (ziv-aflibercept)	Positive change	<p>Remove inclusion criteria: Colorectal Cancer a. Zaltrap (ziv-aflibercept) is being used in members with the following: i. Stage IV unresectable metastatic colorectal cancer AND ii. In combination with irinotecan or with FOLFIRI (fluorouracil, leucovorin, and irinotecan) regimen AND iii. After first progression of advanced or metastatic disease in members not previously receiving irinotecan-based regimens (i.e. FOLFIRI) OR iv. After first progression, within the past 12 months, of adjuvant FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) regimen.</p>
UM ONC_1226	Zaltrap (ziv-aflibercept)	Negative change	<p>Add exclusion criteria: 1. NOTE: Per NCH Policy & NCH Pathway Zaltrap (ziv-aflibercept) is a NON-PREFERRED drug for metastatic colorectal cancer. Please refer to the NCH Pathway document to see the most current recommended regimens/agents for colorectal cancer. 2. Disease progression while taking Zaltrap (ziv-aflibercept).</p>

			Remove exclusion criteria: Zaltrap (ziv-aflibercept) is not being used in members with any of the following: b. As first line therapy without resistance to or has progressed following an oxaliplatin-based regimen or irinotecan-based regimen. c. Within 4 weeks prior to and 4 weeks following surgery and not until surgical wound is fully healed.
UM ONC_1226	Zaltrap (ziv-aflibercept)	Positive change	
UM ONC_1240	Synribo (omacetaxine)	Formatting change	Formatting change
UM ONC_1250	Tafinlar (dabrafenib)	Negative change	Add inclusion criteria: Melanoma: Tafinlar (dabrafenib) may be used in combination with Mekinist (trametinib) in members who have intolerance to/contraindication to the use of [Cobimetinib+Vemurafenib].
UM ONC_1250	Tafinlar (dabrafenib)	Negative change	Add exclusion criteria: Treatment exceeds the maximum limit of 180 (50 mg) tablets/month or 120 (75 mg) tablets/month.
UM ONC_1263	Keytruda (pembrolizumab)	Negative change	Add exclusion criteria: Dosing exceeds single dose limit of Keytruda (pembrolizumab) 400 mg/m2 every 6 weeks or 200 mg/m2 every 3 weeks.
UM ONC_1271	Farydak (panobinostat)	Negative change	Add inclusion criteria: 1. NOTE: PANOBINOSTAT containing regimens are NON-PREFERRED for use in relapsed/refractory multiple myeloma 2. The member received at least 1-3 prior therapies including bortezomib and an immunodulatory agent (i.e. thalidomide, lenalidomide, or pomalidomide)
UM ONC_1271	Farydak (panobinostat)	Positive change	Remove exclusion criteria: QTcF >450 msec or clinically significant baseline ST-segment or T-wave abnormalities.
UM ONC_1274	Opdivo (nivolumab)	Negative change	Add inclusion criteria: 8. Non-Small Cell Lung Cancer NOTE: The combination of [Yervoy(ipilimumab + Opdivo(nivolumab))] for metastatic Non-Small Cell Lung Cancer, in the first line/subsequent line setting, is a Non-Preferred combination per NCH Policy and NCH Pathway. Please refer to the NCH Pathway document for the most current recommended regimens/agent for metastatic Non- Small Cell Lung Cancer.
UM ONC_1297	Venclexta (venetoclax)	Negative change	Add inclusion criteria: 1. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) NOTE#1: Please refer to the NCH Pathway document for the latest recommended regimens for CLL 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 a. Venclexta (venetoclax) may be used as a single agent or in combination with rituximab for relapsed or refractory disease, with or without del(17p)/TP53 mutation 3. Mantle Cell Lymphoma NOTE: Please refer to the NCH Pathway document for the latest recommended treatment options for Mantle Cell Lymphoma. a. Venetoclax may be used as a single agent for relapsed/refractory Mantle Cell Lymphoma, if the patient is intolerant to/ has a contraindication to/ has experienced disease progression on any of the NCH Pathway recommended therapies.

UM ONC_1297	Venclexta (venetoclax)	Positive change	Remove inclusion criteria: Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) a. Venclexta (venetoclax) is being used as any of the following: i. First line therapy in combination with obinutuzumab
UM ONC_1297	Venclexta (venetoclax)	Positive change	Add inclusion criteria: 2. Acute Myeloid Leukemia (AML) Venclexta (venetoclax) is being used in combination with decitabine or azacitidine for: Remission induction therapy & post-remission therapy for members with unfavorable-risk cytogenetics/members unsuitable for intensive remission induction therapy/members who decline intensive therapy
UM ONC_1297	Venclexta (venetoclax)	Positive change	Remove exclusion criteria: Concomitant use with strong CYP3A4/5 inhibitors during initiation and dose escalation phase.
UM ONC_1297	Venclexta (venetoclax)	Negative change	Add exclusion criteria: 2. Exclusions described above for specific diagnoses 4. Treatment exceeds the maximum limit of 120 (100 mg) or 240 (50 mg) tablets per month Add inclusion criteria: Ovarian cancer: NOTE: Rucaparib is a non-preferred PARP-inhibitor per NCH Policy & NCH Pathway. Please refer to the NCH Pathway document for the most current recommended PARP inhibitors for ovarian cancer Rucaparib may be used as a single agent when ALL of the following criteria are met: a. The member has stage III/IV ovarian carcinoma Prostate Cancer: Rucaparib may be used as a single agent in prostate cancer when ALL the following criteria are met: a. Member has metastatic Castration-Resistant prostate Cancer, AND b. Member has experienced disease progression on or after taxane based therapy(e.g. docetaxel), AND Androgen Receptor Directed therapy (e.g. Abiraterone and/or Enzalutamide), AND c. Member's cancer is positive for BRCA 1 or 2 mutation (on germline testing- on the patient and/or somatic testing on the tumor tissue)
UM ONC_1301	Rubraca (rucaparib)	Negative change	Add exclusion criteria: 2. Lack of documented BRCA1 or 2 testing: Germline testing for members with Ovarian Cancer, AND Germline and/or somatic mutation testing on the tumor tissue
UM ONC_1301	Rubraca (rucaparib)	Negative change	Add inclusion criteria: has had complete or partial response/remission following platinum – based chemotherapy, when being used as maintenance therapy in the first line setting
UM ONC_1307	Zejula (niraparib)	Negative change	
UM ONC_1324	Kymriah (tisagenlecleucel)	Positive change	Remove exclusion criteria: 1. Kymriah (tisagenlecleucel) is being used after disease progression with the same regimen or prior anti-CD19 therapy. 2. Concurrent use with corticosteroids, chemotherapy, anti-T cell, or GVHD therapies. Replacement doses of < 12 mg/m2/day hydrocortisone or equivalent is allowed. 3. Dosing exceeds single max dose of 6 X 10 ⁸ CAR-positive viable T-cells. 4. Active or any uncontrolled infection and inflammatory disorders.
UM ONC_1329	Yescarta (axicabtagene ciloleucel)	Formatting change	Formatting change
UM ONC_1342	Azedra (iobenguane I-131)	Positive change	Add inclusion criteria: MIBG (meta-iodobenzylguanidine)

UM ONC_1324	Kymriah (tisagenlecleucel)	Negative change	<p>Add exclusion criteria: 1. Kymriah (tisagenlecleucel) is being used after disease progression on or after CAR-T cell therapy directed towards CD19 antigen (Kymriah or Yescarta)</p> <p>Remove inclusion criteria: Immune Thrombocytopenic Purpura</p> <p>a. Tavalisse (fostamatinib) is being used for ALL of the following:</p> <p>i. Persistent or chronic ITP for at least 3 months and no known etiology for thrombocytopenia</p> <p>ii. Insufficient response to previous treatment: corticosteroids, immunoglobulins, splenectomy, and/or a thrombopoietin receptor agonist.</p> <p>iii. Average platelet count < 30,000/μL from at least 3 qualifying counts</p> <p>iv. Has failed, contraindications, or intolerance to Nplate or Promacta.</p>
UM ONC_1345	Tavalisse (fostamatinib)	Positive change	<p>Remove inclusion criteria: Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)</p> <p>a. The member has BPDCN and Elzonris (tagraxofusp) is being used as a single agent AND</p> <p>b. Has adequate cardiac function with a left ventricular ejection fraction (LVEF) \geq 40% as measured by MUGA scan or 2-D ECHO AND</p> <p>c. Prior to administering the first dose in cycle 1 ALL of the following:</p> <p>i. A serum albumin level of 3.2 g/dL or greater</p> <p>ii. Serum creatinine \leq 1.5 mg/dl</p> <p>iii. Bilirubin \leq 1.5 mg/dl</p> <p>iv. AST and ALT \leq 2.5 times the upper limit of normal (ULN).</p> <p>Add inclusion criteria: 1. Immune Thrombocytopenic Purpura</p> <p>Tavalisse (fosamatinib) may be used as a single agent, or in combination with one concomitant ITP medication (limited to one : corticosteroids < 20 mg prednisone/equivalent daily, azathioprine, or danazol) when ALL of the following criteria have been satisfied:</p> <p>a. Members with Chronic ITP, AND</p> <p>b. Insufficient response (defined by failure of platelet count to increase and stay above 30,000)to prior therapies including corticosteroids, IVIgG, splenectomy/rituxan, and/or a Thrombopoietin Receptor Agonist (romiplostim, eltrombopag or avatrombopag)</p> <p>c. Platelet count \leq 30K prior to start of therapy</p> <p>Add exclusion criteria:</p> <p>1. Patient has not had a documented trial and failure of prior ITP therapies as described above</p>
UM ONC_1356	Elzonris (tagraxofusp)	Positive change	<p>Treatment exceeds the maximum limit of 60 (150 mg) or 60 (100 mg) tablets/month.</p> <p>Remove exclusion criteria:</p> <p>The member has any of the following:</p> <p>a. Clinical diagnosis of autoimmune hemolytic anemia</p> <p>b. Uncontrolled or poorly controlled hypertension</p> <p>POLICY#UM ONC_1345</p> <p>PROPRIETARY & CONFIDENTIAL</p> <p>UM ONC_1345 Tavalisse (fostamatinib)_12112019 Page 2 of 4</p> <p>c. History of coagulopathy including prothrombotic conditions.</p> <p>2. Rescued treatment was used after 10 weeks of treatment (this is defined as non-responders).</p> <p>3. If platelet counts is < 50 x 10⁹/L or if the platelet count does not increase to a point sufficient to avoid clinically important bleeding after 12 weeks of therapy.</p>
UM ONC_1345	Tavalisse (fostamatinib)	Negative change	<p>Remove exclusion criteria:</p> <p>The member has any of the following:</p> <p>a. Clinical diagnosis of autoimmune hemolytic anemia</p> <p>b. Uncontrolled or poorly controlled hypertension</p> <p>POLICY#UM ONC_1345</p> <p>PROPRIETARY & CONFIDENTIAL</p> <p>UM ONC_1345 Tavalisse (fostamatinib)_12112019 Page 2 of 4</p> <p>c. History of coagulopathy including prothrombotic conditions.</p> <p>2. Rescued treatment was used after 10 weeks of treatment (this is defined as non-responders).</p> <p>3. If platelet counts is < 50 x 10⁹/L or if the platelet count does not increase to a point sufficient to avoid clinically important bleeding after 12 weeks of therapy.</p>
UM ONC_1345	Tavalisse (fostamatinib)	Positive change	<p>Remove exclusion criteria:</p> <p>The member has any of the following:</p> <p>a. Clinical diagnosis of autoimmune hemolytic anemia</p> <p>b. Uncontrolled or poorly controlled hypertension</p> <p>POLICY#UM ONC_1345</p> <p>PROPRIETARY & CONFIDENTIAL</p> <p>UM ONC_1345 Tavalisse (fostamatinib)_12112019 Page 2 of 4</p> <p>c. History of coagulopathy including prothrombotic conditions.</p> <p>2. Rescued treatment was used after 10 weeks of treatment (this is defined as non-responders).</p> <p>3. If platelet counts is < 50 x 10⁹/L or if the platelet count does not increase to a point sufficient to avoid clinically important bleeding after 12 weeks of therapy.</p>

UM ONC_1359	Arranon (nelarabine)	Positive change	Remove inclusion criteria: A component of COG AALL0434 regimen (daunorubicin, vincristine, prednisone, and pegaspargase; nelarabine consolidation therapy).
UM ONC_1359	Arranon (nelarabine)	Positive change	Remove exclusion criteria: 1. Arranon (nelarabine) is being used after disease progression with the same regimen. 3. Member with central nervous system (CNS) disease. 4. Dosing exceeds single dose limit of Arranon (nelarabine)
UM ONC_1359	Arranon (nelarabine)	Negative change	Add exclusion criteria: 1. Arranon (nelarabine) is being used after disease progression while receiving Arranon(nelarabine) or a regimen containing Arranon(nelarabine)
UM ONC_1360	Piqray (alpelisib)	Negative change	Add inclusion criteria: Breast cancer Piqray is not a preferred agent per NCH Policy and NCH Pathway. Please refer to the NCH Pathway document to see the preferred regimens/agents for first and subsequent lines of therapy in metastatic ER/PR positive breast cancer. Piqray(alpelisib) may be used if ALL the following criteria are satisfied: a. Member (includes both men and women- postmenopausal or premenopausal and receiving concurrent ovarian suppression) has ER/PR positive and HER-2 negative metastatic/advanced breast cancer, AND b. Member's cancer is positive for a PIK3CA- mutation, confirmed by tissue biopsy and/or liquid biopsy(either by the companion diagnostic test theascreen PIK3CA mutation test OR another valid equivalent test), AND c. Piqray(alpelisib) will be used in combination with Fulvestrant, AND d. Member has experienced disease progression on or after therapy with an aromatase inhibitor
UM ONC_1360	Piqray (alpelisib)	Positive change	Remove inclusion criteria: Breast Cancer a. The member has recurrent/metastatic breast cancer and Piqray (alpelisib) is being used as ALL of the following: i. If female, patient is postmenopausal ii. Has identified hormone receptor positive, human epidermal growth factor receptor 2 (HER2)-negative, and PIK3CA- mutated status iii. Relapse with documented progression while on or after at least one line of endocrine therapy iv. Has non-visceral or asymptomatic visceral disease.
UM ONC_1360	Piqray (alpelisib)	Negative change	Add exclusion criteria: 1. Disease progression while receiving Piqray (alpelisib) and Fulvestrant combination therapy 2. Concurrent use with other anti-cancer therapy other than Fulvestrant
UM ONC_1360	Piqray (alpelisib)	Positive change	Remove exclusion criteria: 1. Piqray (alpelisib) is being used after disease progression with the same regimen, fulvestrant, or PI3K, or mTOR inhibitor (e.g. everolimus). 2. Concurrent use with other chemotherapy. 3. Member with any of the following: a. Child pugh score B or C b. An established diagnosis of diabetes mellitus type I or not controlled type II c. History of pancreatitis.

UM ONC_1361	Erwinaze (asparaginase Erwinia chrysanthemi)	Positive change	<p>Remove inclusion criteria: Acute Lymphoblastic Leukemia (ALL) a. The member has ALL and Erwinaze (asparaginase Erwinia chrysanthemi) is being used for the following: i. Philadelphia chromosome-negative ALL 1. As Induction therapy in: a. PETHEMA-based regimen such as ALLOLD07 (vincristine, dexamethasone, idarubicin, cyclophosphamide, cytarabine, methotrexate, and L-asparaginase) b. Modified DFCI 91-01 protocol: dexamethasone, doxorubicin, vincristine, methotrexate, cytarabine, L-asparaginase, and IT chemotherapy) OR ii. Philadelphia chromosome-positive ALL 1. Induction therapy in: EWALL (vincristine, dexamethasone, methotrexate, cytarabine, asparaginase) + TKI (dasatinib, nilotinib)</p>
UM ONC_1361	Erwinaze (asparaginase Erwinia chrysanthemi)	Negative change	<p>Add inclusion criteria: 1. Acute Lymphoblastic Leukemia (ALL) NOTE: PEGASPARGASE is preferred over Erwinaze in the treatment of ALL. Please refer to the NCH Pathway document to see the most current recommended regimens/agents for ALL - The member has ALL- Acute Lymphoblastic Leukemia and has a demonstrated hypersensitivity to pegaspargase a. The member has ALL and has a demonstrated hypersensitivity to E.coli derived asparaginase AND b. Erwinaze (asparaginase Erwinia chrysanthemi) is being used for the following: Philadelphia chromosome-negative ALL/Philadelphia chromosome positive ALL as a part of a multi-agent chemotherapy regimen Remove exclusion criteria: Prior history of serious hypersensitivity reactions, pancreatitis, thrombosis, or hemorrhagic events. Erwinaze can be substituted for pegaspargase in cases of systemic allergic reaction or anaphylaxis due to pegaspargase hypersensitivity</p>
UM ONC_1361	Erwinaze (asparaginase Erwinia chrysanthemi)	Positive change	
UM ONC_1356	Elzonris (tagraxofusp)	Negative change	<p>Add inclusion criteria: 1. Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) a. The member has BPDCN and Elzonris (tagraxofusp) will be used as a single agent in adults and pediatric patients 2 years and older AND b. Elzonris (tagraxofusp) will be used as treatment for induction, post-remission, or relapsed/refractory BPDCN. Remove inclusion criteria: Tenosynovial Giant Cell Tumor (TGCT) a. The member has TGCT associated with severe morbidity or functional limitations and not amenable to improvement with surgery AND b. Has adequate hematologic, hepatic, and renal function, defined by: i. ANC $\geq 1.5 \times 10^9/L$ ii. AST/ALT $\leq 1.5 \times$ upper limit of normal (ULN) iii. Hemoglobin > 10 g/dL iv. Total bilirubin $\leq 1.5 \times$ ULN v. Platelet count $\geq 100 \times 10^9/L$ vi. Serum creatinine $\leq 1.5 \times$ ULN</p>
UM ONC_1364	Turalio (pexidartinib)	Positive change	

UM ONC_1364	Turalio (pexidartinib)	Negative change	<p>Add inclusion criteria: Tenosynovial Giant Cell Tumor (TGCT)</p> <p>a. The member has TGCT associated with severe morbidity or functional limitations and not amenable to improvement with surgery, or patient is not a surgical candidate AND</p> <p>b. Turalio (pexidartinib) will be used as a single agent for non-malignant TGCT.</p> <p>Add exclusion criteria:</p> <ol style="list-style-type: none"> 1. Disease progression while receiving Turalio(pexidaritinb) 2. Not to be used in members with pre-existing increased serum transaminases; total bilirubin or direct bilirubin (>ULN); or active liver or biliary tract disease, including increased alkaline phosphatase.
UM ONC_1364	Turalio (pexidartinib)	Negative change	<p>Remove exclusion criteria:</p> <ol style="list-style-type: none"> 1. Disease progression with any biologic treatment targeting CSF-1 or the CSF-1R. 2. Presence of detectable metastases. 3. Active or chronic infection with hepatitis C virus (HCV), hepatitis B virus, known active or chronic infection with human immunodeficiency virus, or known active tuberculosis.
UM ONC_1364	Turalio (pexidartinib)	Positive change	