Policy #	Drug(s)	Type of Change	Brief Description of Policy Change
New	Breyanzi (lisocabtagene maraleucel)	n/a	n/a
New	Ukoniq (umbralisib)	n/a	n/a
New	Tepmetko (tepotinib)	n/a	n/a
UM ONC_1035	5HT3 Receptor Antagonists	Negative change	Add inclusion criteria: Note: Per NCH policy, generic intravenous Emend (fosaprepitant) + 5HT3 receptor antagonist [e.g., Zofran (ondansetron), Kytril (granisetron), or Aloxi (palonosetron)] are preferred over Akynzeo (netupitant-palonosetron), Sancuso (granisetron patch), or Sustol (granisetron extended release) for moderately/highly emetogenic chemotherapy. Exception: Failure/Intolerance to any of the above preferred combinations, OR refractory delayed nausea/emesis despite any of the above preferred combinations.
UM ONC_1035	5HT3 Receptor Antagonists	Negative change	Add exclusion criteria: single max dose limit for Akynzeo 300 mg/0.5 mg (oral) or 235 mg/0.25 mg (IV)
UM ONC_1130	Alimta (pemetrexed)	Negative change	Add exclusion criteria: B.Disease progression on Alimta or an Alimta containing regimen.
UM ONC_1134	Trastuzumab Products and Phesgo	Positive change	Remove inclusion criteria: B.HER-2 Positive Breast Cancer i.NOTE: [Pertuzumab + Trastuzumab] is indicated only in patients with ~~a tumor size 2 cm or higher,~~ node positive disease ~~or ER/PR negative disease~~.
UM ONC_1194	Nexavar (soraferib)	Negative change	Add inclusion criteria: 2. Renal Cell Carcinoma (RCC) NOTE: The preferred tyrosine kinase inhibitor, per NCH Policy & NCH Pathway in the subsequent line of therapy for advanced or metastatic RCC, is Cabometyx (cabozantinib) over Nexavar (sorafenib). 3.Hepatocellular Carcinoma (HCC) a.The preferred agents, per NCH Policy & NCH Pathway, for unresectable or metastatic HCC are as follows: i.For first line treatment: Tecentriq (atezolizumab) + Avastin (bevacizumab).
UM ONC_1194	Nexavar (soraferib)	Positive change	Remove inclusion criteria: Remove preferred Lenvima for HCC
UM ONC_1194	Nexavar (soraferib)	Positive change	Remove exclusion criteria: 1.Off-label indications for Nexavar (sorafenib) in soft tissue sarcoma.
UM ONC_1197	Sutent (sunitnib)	Negative change	Add inclusion criteria: 2. Renal cell carcinoma (RCC) NOTE: The preferred tyrosine kinase inhibitor, per NCH policy and NCH pathway for advanced or metastatic RCC, IMDC Good Risk disease, is Votrient (pazopanib). The latter recommendation is based upon the data from the COMPARZ trial. 3.Gastrointestinal stromal tumor (GIST) a.Sutent (sunitinib) may be used as a single agent in members with unresectable, recurrent, or metastatic GIST who have disease progression on OR, contraindications to, OR intolerance to generic imatinib. 4.Pancreatic Neuroendocrine tumor (PNET) - use for any line of therapy.
UM ONC_1197	Sutent (sunitnib)	Positive change	Remove inclusion criteria: 4.Pancreatic Neuroendocrine tumor (PNET) a.NOTE: The preferred agents, per NCH Policy and pathway, for first line and subsequent treatment of pancreatic neuroendocrine tumor are Everolimus and Sunitinib, respectively.
UM ONC_1197	Sutent (sunitnib)	Positive change	Remove exclusion criteria: 1.Off-label indications for Sutent (sunitinib) in soft tissue sarcoma and thyroid carcinoma. 2.Dosing exceeds single dose limit of Sutent (sunitinib) 50 mg. 3.For adjuvant therapy: do not exceed nine 6- week cycles.
UM ONC_1204	Caprelsa (vandetanib)	Negative change	Add exclusion criteria: 3.Treatment exceeds the maximum limit of 90 (100 mg) or 30 (300 mg) tablets/month.
UM ONC_1206	Xalkori (crizotinib)	Positive change	Add inclusion critiera: ALK+ Anaplastic Lymphoma 1.Xalkori(crizotinib) may be used as a single agent for members 21 years old or younger with Anaplatic Lymphoma that is: a.Positive for ALK- Anaplastic Lymphoma Kinase (confirmed by testing), AND b.The member has experienced disease progression on at least one prior therapy.
UM ONC_1216	Perjeta (pertuzumab)	Negative change	Add inclusion criteria: Breast cancer i.Pertuzumab + trastuzumab + chemotherapy is indicated only in members with ~~a tumor size 2 cm or higher,~~ node positive disease ~~, or ER/PR negative disease~~ (confirmed either by radiographic imaging e.g. breast MRI and/or a needle aspirate/biopsy of a suspicious axillary node).
UM ONC_1216	Perjeta (pertuzumab)	Negative change	Add exclusion criteria: B.The member has node negative disease.
UM ONC_1232	Stivarga (regorafenib)	Positive change	Add inclusion critiera: GIST disease progression on generic imatinib therapy OR have contraindications/intolerance to imatinib AND sunitinib.
UM ONC_1232	Stivarga (regorafenib)	Positive change	Remove exclusion criteria: 1.Concurrent use with other chemotherapy.
UM ONC_1242	Jakafi (ruxolitinib)	Positive change	Remove inclusion criteria: B.Myelofibrosis 1.NOTE: The preferred agent, per NCH Policies, is Jakafi (ruxolitinib) for all of the following indications.
UM ONC_1283	Lenvima (lenvatinib)	Negative change	Add inclusion criteria: 3.Renal Cell Carcinoma (RCC) 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 who have experienced disease progression on prior therapy with an anti-angiogenesis agent (an oral TKI and/or bevacizumab). 4.Hepatocellular Carcinoma (HCC) a.NOTE: The preferred regimen agent, per NCH Policies & NCH Pathway, for first line therapy of unresectable or metastatic HCC is [Tecentriq (atezolizumab) + Avastin (bevacizumab). Lenvima (lenvatinib) is preferred for members with no worse than Child-Turcotte-Pugh class A cirrhosis. 5.Endometrial Cancer a.NOTE : For members with recurrent/metastatic endometrial carcinoma with tumors that are MSI-High, single agent pembrolizumab is preferred as second/subsequent line therapy over [lLenvatinib+pembrolizumab]. This recommendation is based on the lack of Level 1 evidence to show the superiority of [lenvatinib+pembrolizumab] over single agent pembrolizumab in this subgroup.

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UM ONC_1283	Lenvima (lenvatinib)	Positive change	Add inclusion critiera: 5.Endometrial Cancer envima (lenvatinib) is being used in combination with pembrolizumab as subsequent line therapy after disease progression on prior chemotherapy, if not a candidate for curative surgery or radiotherapy, in members with recurrent/metastatic endometrial cancer whose tumors are MSI-Stable.
UM ONC_1283	Lenvima (lenvatinib)	Positive change	Remove exclusion criteria: 2.Prior therapy of lenvatinib or (mTOR) inhibitor.
UM ONC_1283	Lenvima (lenvatinib)	Negative change	Add exclusion criteria:5.Treatment exceeds the maximum monthly limit of 30 (24 mg per day carton); 30 (20 mg per day carton); 30 (18 mg per day carton); 30 (14 mg per day carton); 30 (10 mg per day carton); 30 (8 mg per day carton), 30 (4 mg per day carton).
UM ONC_1314	Imfinzi (durvalumab)	Negative change	Remove inclusion criteria: 2.Urothelial Carcinoma a.NOTE: Per NCH policy and NCH pathway, the checkpoint inhibitor of choice is Keytruda over Opdivo, Tecentriq, Bavencio, or Imfinzi. Please refer to the NCH Pathway document.
UM ONC_1314	Imfinzi (durvalumab)	Negative change	a.NOTE: Per NCH Policy and NCH Pathway, the preferred checkpoint inhibitor for first line therapy of Extensive Stage Small Cell Lung Cancer is Tecentriq. Please refer to the NCH Pathway document. This recommendation is based on the lack of Level 1 evidence to support superior outcomes with Imfinzi (durvalumab)-based therapy over Tecentriq (atezolizumab)-based therapy, in first line treatment of extensive- stage small cell lung cancer.
UM ONC_1350	Vitrakvi (larotrectinib)	Negative change	Add inclusion criteria:
UM ONC_1362	Polivy (polatuzumab vedotin)	Positive change	Remove inclusion criteria: 2.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). d.Has failed at least 2 prior therapies,
UM ONC_1362	Polivy (polatuzumab vedotin)	Positive change	Add inclusion critiera: Has failed at least one or more prior therapies for DLBCL
UM ONC_1362	Polivy (polatuzumab vedotin)	Positive change	Add exclusion criteria: 1.Polivy (polatuzumab vedotin) use after disease progression with the same regimen or prior bendamustine unless therapy was completed more than a year ago.
UM ONC_1366	Inrebic (fedratinib)	Positive change	Add inclusion critiera: 2.Myelofibrosis (MF) a.The member has primary myelofibrosis or secondary myelofibrosis
UM ONC_1366	Inrebic (fedratinib)	Positive change	Remove inclusion criteria: d.The member has failed prior therapy with Jakafi (ruxolitinib).
UM ONC_1367	Rozlytrek (entrectinib)	Negative change	Add inclusion criteria: 2.NTRK-Fusion Positive Metastatic Solid Tumors a.NOTE: The preferred agent, per NCH Policy & NCH Pathway, for NTRK gene fusion positive recurrent, advanced, or metastatic solid tumors is Rozlytrek (entrectinib) over Vitrakvi (larotrectinib). Above recommendation is based on the lack of Level 1 evidence to show the superiority of Vitrakavi (larotrectinib) over Rozlytrek (entrectinib).
UM ONC_1367	Rozlytrek (entrectinib)	Positive change	Remove 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.
UM ONC_1373	Endari (l-glutamine)	Negative change	Add inclusion criteria: B.Sickle Cell Disease 1.Endari (l-glutamine) may be used with or without hydroxurea in members 5 years of age and older with sickle cell disease (and related genotypes of Sickle Cell Disease) related complications, including pain crisis or acute chest syndrome within the past 12 months.
UM ONC_1373	Endari (l-glutamine)	Positive change	Remove inclusion criteria: a.Two documented episodes of sickle cell disease related crises, including pain or acute chest syndrome, within 12 months b.INR is ≤ 2.0 c.Serum Albumin ≥ 3.0.
UM ONC_1373	Endari (l-glutamine)	Positive change	Remove exclusion criteria: B.Concurrent use with other anti-sickling medication within 3 months of diagnosis (e.g. hydroxyurea).
UM ONC_1375	Adakveo (crizanlizumab)	Negative change	Add inclusion criteria: B.Sickle Cell Disease 1.Adakveo (crizanlizumab) is being used in members aged 16 -65 years with Sickle cell disease (HbSS, HbSC, HbS/beta0-thalassemia, HbS/beta+-thalassemia, and other less common genotypes)
UM ONC_1376	Oxbryta (voxelotor)	Negative change	Add inclusion criteria: 2.Sickle Cell Disease (including Homozygous Hemoglobin S, sickle Hemoglobin C disease, Hemoglobin S Beta-Thalassemia, or other genotypic variants of Sickle Cell Disease) a.Oxbryta (voxelotor) will may be used in members 12 years of age and older with a Hgb level of 5.5-10.5 gm/dl, prior therapy with hydroxyurea for 3 months, and a history of 1 or more vaso-occlusive crises in the past 12 months. Oxbryta (voxelotor) may be used with or without hydroxyurea.
UM ONC_1376	Oxbryta (voxelotor)	Positive change	i.prior use and failure of Hydroxyurea ii.At least one episode of vaso-occlusive crisis (VOC) in the past 12 months. VOC event is defined as an acute episode of pain that required a medical facility visit and treatment with oral or parenteral pain medications
UM ONC_1376	Oxbryta (voxelotor)	Positive change	Remove exclusion criteria: 1.Inadequate clinical improvement with Oxbryta (voxelotor). 2.Hemoglobin < 5.5 g/dL.
UM ONC_1393	Sarclisa (isatuximab-irfc)	Negative change	Add inclusion criteria: 2.Multiple Myeloma (MM) a.NOTE: The preferred anti-CD38 agent, per NCH Policies, is Darzalex (daratumumab). This recommendation is based on a lack of Level 1 evidence showing superior patient outcomes with Sarclissa (isatuximab-irfc) vs Dazrzalex (daratumumab).
UM ONC_1393	Sarclisa (isatuximab-irfc)	Positive change	Remove inclusion criteria: (daratumumab). iii.after progression on 3 prior lines of therapy or double refractory
UM ONC_1393	Sarclisa (isatuximab-irfc)	Positive change	Add inclusion critiera: ii.Member has received prior therapy with a proteasome inhibitor and an immunomodulatory agent other than Pomalyst
UM ONC_1393	Sarclisa (isatuximab-irfc)	Negative change	Add exclusion criteria: Sarclisa (isatuximab-irfc) is being used after disease progression with the same regimen OR after disease progression on a daratumumab -based regimen.