Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
NEW	Opdualag (nivolumab and relatlimab-rmbw)	N/A	N/A	N/A
NEW	Pluvicto (lutetium Lu 177 vipivotide tetraxetan)	N/A	N/A	N/A
UM ONC_1130	Alimta (Pemetrexed)	Positive change	Remove inclusion criteria: B.Non-Small Cell Lung Cancer (NSCLC) 1.The member has recurrent or metastatic non-squamous NSCLC and Alimta or Pemfexy (pemetrexed) may be used for ANY of the following: a.First line therapy ~~for EGFR & ALK negative disease~~ in combination with carboplatin/cisplatin with or without pembrolizumab	Per FDA labeling
UM ONC_1195	Votrient (pazopanib)	Positive change	Remove inclusion criteria: B.Advanced/Metastatic Renal Cell Carcinoma: remove all histology reference	Per Compendia Listing
UM ONC_1195	Votrient (pazopanib)	Negative change	Add inclusion criteria: C.Advanced Soft Tissue Sarcoma 1.Palliative therapy for recurrent or metastatic non-adipocytic soft tissue sarcoma as a single agent, as ~~first line/~~subsequent line therapy.	Per FDA labeling
UM ONC_1195	Votrient (pazopanib)	Negative change	Add exclusion criteria: A.The member has stage I-III RCC, adipocytic soft tissue sarcoma, or gastrointestinal stromal tumors. B. Votrient (pazopanib) is being used concurrently with other chemotherapy anticancer therapy.	Per FDA labeling
UM ONC_1196	Sprycel (dasatinib)	Positive change	Remove inclusion criteria: 1.Sprycel (dasatinib) may be used as a single agent for adult and pediatric members 1 year of age and older with ~~newly diagnosed~~ CML (Ph-1+ Philadelphia chromosome positive or BCR-ABL positive) ~~who are intolerant/have a contraindication to generic imatinib or have experienced disease progression on generic imatinib~~ C.GIST 1.As a single agent for advance/metastatic GIST- Gastrointestinal Stromal Tumor- with a positive PDGFRA D842V mutation when member has experienced disease progression on Gleevec (imatinib), Sutent (sunitinib), or Stivarga (regorafenib).	Per FDA labeling
UM ONC_1196	Sprycel (dasatinib)	Negative change	Add includion criteria: 2. NOTE: Per NCH Pathway & NCH Policy, Sprycel (dasatinib) is non-Preferred for the treatment of newly diagnosed Philadelphia chromosome positive or BCR-ABL positive CML. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes compared to generic imatinib for the above setting.	Per NCH Pathway exclusion
UM ONC_1196	Sprycel (dasatinib)	Negative change	Add exclusion criteria: B.Sprycel (dasatinib) is being used on Philadelphia or BCR-ABL negative CML /ALL or in members with the following mutations of BCR-ABL1: T315I/A, F317L/V/I/C or V299L.	Per FDA labeling
UM ONC_1196	Sprycel (dasatinib)	Positive change	Remove exclusion criteria: C.Members with GIST with no history of failure or intolerance to Sutent (sunitinib), Gleevec (imatinib), or Stivarga (regorafenib). D.Sprycel (dasatinib) is being used concurrently with other tyrosine kinase inhibitors.	Per FDA labeling
UM ONC_1200	Torisel (temsrolimus)	Positive change	Remove inclusion criteria: B.Renal Cell Carcinoma (RCC) 1. Torisel is only recommended may be used as monotherapy for relasped/refractory metastatic ~~clear cell~~ renal cell carcinoma~~, in members who have failed two oral TKIs and one or more Immune Checkpoint Inhibitor.~~	Per FDA labeling
UM ONC_1200	Torisel (temsrolimus)	Negative change	Add inclusion criteria: B.Renal Cell Carcinoma (RCC) 2.NOTE: Per NCH Pathway & NCH Policy, Torisel (temsirolimus) is a non-Preferred drug for the treatment of RCC. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes compared to oral Tyrosine Kinase Inhibitors [e.g., Cabometyx (cabozantinib), Votrient (pazopanib)] AND an Immune Checkpoint Inhibitor [e,g., (nivolumab) ± Yervoy (ipilimumab)].	Per NCH Pathway exclusion
UM ONC_1207	Zelboraf (vemurafenib)	Positive change	Remove inclusion criteria: B.Malignant Melanoma 1. ~~NOTE: Per NCH Policy & NCH Pathway,~~ Zelboraf (vemurafenib) + Cotellic (cobimetinib) ~~is the preferred~~ may be used as combination therapy for BRAF V600E mutation positive melanoma, both in the first line and subsequent line settings. 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. C.Erdheim-Chester Disease (ECD) 1.Zelboraf (vemurafenib) may be used as a single agent in member with BRAF V600E mutation positive ECD.	Per NCH Pathway exclusion and expansion
UM ONC_1207	Zelboraf (vemurafenib)	Negative change	Add exclusion criteria: A.Disease progression on the same regimen or with another combination of a BRAF inhibitor (i.e., encorafenib or dabrafenib) and MEK inhibitor (i.e., binimetinib or trametinib).	Per FDA labeling
UM ONC_1207	Zelboraf (vemurafenib)	Positive change	Remove exclusion criteria: B.Use of Zelboraf (vemurafenib) in combination with Cotellic (cobimetinib) + Tecentriq (atezolizumab) in metastatic/recurrent/unresectable BRAF V600 mutation positive malignant melanoma.	Per FDA labeling

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UM ONC_1240	Synribo (omacetaxine)	Positive change	Remove inclusion criteria: B.Chronic Myelogenous Leukemia (CML) 2.The member is Philadelphia chromosome or BCR-ABL positive AND a.The member has experienced disease progression/intolerance to ~~three~~ two or more of the following tyrosine kinase inhibitors, including : Gleevec (imatinib) generic imatinib AND, Tasigna (nilotinib), ~~Bosulif (bosutinib),~~ or Sprycel (dasatinib) ~~OR~~ ~~b.The member has a T315I mutation positive CML and has failed Iclusig (ponatinib) to treat CML with this mutation.~~ ~~3.NOTE: Per NCH Pathway & NCH Policy, Synribo (omacetaxine) is a non-Preferred drug for the treatment of CML. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with Synribo (omacetaxine) compared to NCH Preferred regimens. Please refer to NCH Pathway for the preferred treatments recommended in CML.~~	Per FDA labeling
UM ONC_1240	Synribo (omacetaxine)	Negative change	Add exclusion criteria: B.Concurrent use with other anticancer therapy~~.Gleevec (imatinib), Sprycel (dasatinib), Tasigna (nilotinib), or Bosulif (bosutinib).~~	Per Clinical Trial Analysis/Criteria
UM ONC_1241	Iclusig (ponatinib)	Positive change	Remove inclusion criteria: B.Chronic Myeloid Leukemia (CML) ~~1.NOTE: Per NCH Policy & NCH Pathway, generic imatinib is the preferred agent for initial or subsequent treatment of Philadelphia chromosome/BCR-ABL positive CML. Please refer to UM ONC_1177 Gleevec (imatinib mesylate) policy.~~ 1.Iclusig (ponatinib) may be used as single agent for ~~all lines of~~ subsequent line therapy if there is documented intolerance, contraindications, or disease progression on generic imatinib and one of the following 2nd generation Tyrosine Kinase Inhibitors (TKIs): Tasigna (nilotinib) or Sprycel (dasatinib)~~, or Bosulif (bosutinib)~~ OR 3.2.Iclusig (ponatinib) may be used as a single agent ~~as initial or subsequent therapy~~ for members with BCR-ABL1 T3151 mutation positive CML.	Per FDA labeling
UM ONC_1241	Iclusig (ponatinib)	Negative change	Add exclusion criteria: B.Iclusig (ponatinib) is not indicated and is not recommended for the treatment of members with newly diagnosed CML without the T3151 mutation.	Per FDA labeling
UM ONC_1241	Iclusig (ponatinib)	Negative change	Add exclusion criteria: C.Concurrent use with other ~~tyrosine kinase inhibitors~~ anticancer therapy for the treatment of CML.	Per FDA labeling
UM ONC_1327	Aliqopa (copanlisib)	Positive change	Remove inclusion criteria: 1.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). 2.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. 3.Until further data are available, Aliqopa (copanlisib) is not recommended for use by NCH Policy.	Per NCH Pathway expansion
UM ONC_1327	Aliqopa (copanlisib)	Positive change	Add inclusion criteria: B.Follicular Lymphoma 1.The member has relapsed/refractory indolent Follicular B Cell Lymphoma grades 1-3a and Aliqopa (copanlisib) may be used following 2 or more prior systemic therapy, including an anti-CD20 based regimen (e.g., rituximab +/- CHOP/bendamustine/CVP).	Per FDA labeling
UM ONC_1327	Aliqopa (copanlisib)	Positive change	Remove exclusion criteria: A.Not recommended	Per NCH Pathway expansion
UM ONC_1327	Aliqopa (copanlisib)	Negative change	Add exclusion criteria: A.Disease progression while taking Aliqopa (copanlisib) or on another PI3K inhibitor [e.g., Zydelig (idelalisib), Copiktra (duvelisib)]. B.Concurrent use with other anticancer therapy. C.Dosing exceeds single dose limit of Aliqopa (copanlisib) 60 mg.	Per FDA labeling
UM ONC_1335	Braftovi (encorafenib)	Positive change	Remove 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. 2.Braftovi (encorafenib) may be used in BRAF V600E or V600K mutation positive unresectable/metastatic melanoma, in combination with Mektovi (binimetinib) ~~, in members who have intolerance/contraindication to Zelboraf (vemurafenib) + Cotellic (cobimetinib).~~	expansion
UM ONC_1360	Piqray (alpelisib)	Negative change	Add exclusion criteria: B.Members with PIK3CA wild type breast cancer.	Per FDA labeling

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UM ONC_1242	Jakafi (ruxolitinib)	Negative change	Add inclusion criteria: B.Myelofibrosis 1.Jakafi (ruxolitinib) will be used as monotherapy in a member with any of the following: primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis AND a platelet count of ≥ 50 × 109/L prior to start of treatment AND. 2.The member has splenomegaly AND 3.The member has intermediate (2 prognostic factors) or high-risk (3 or more prognostic factors) myelofibrosis. The prognostic factors include the following: a.Age > 65 years b.Hemoglobin < 10 g/dL c.Leukocyte > 25 x 109/L d.Circulating blasts ≥ 1% e.Platelet count < 100 x 109LL f.RBC transfusion need g.Unfavorable karyotype +8, -7/7q-, i(17q), inv(3), -5/5q-, 12p-, 11q23.	Per FDA labeling
UM ONC_1242	Jakafi (ruxolitinib)	Negative change	Add exclusion criteria: A.Disease progression while taking Jakafi (ruxolitinib) or another JAK2 inhibitor [e.g., Inrebic (fedratinib)].	Per Clinical Trial Analysis/Criteria
UM ONC_1242	Jakafi (ruxolitinib)	Positive change	Remove exclusion criteria: C.Dosing exceeds single dose limit of Jakafi (ruxolitinib) 25 mg (for Myelofibrosis or Polycythemia Vera) ~~; 10 mg (for Graft-Versus-Host Disease).~~	Other: Out of scope
UM ONC_1376	Oxbryta (voxelotor)	Positive change	Remove exclusion criteria: A.The member continued to require blood transfusion or there was a lack of hemoglobin increase of at least 1gm/dL	Per Clinical Trial Analysis/Criteria
UM ONC_1376	Oxbryta (voxelotor)	Negative change	Add exclusion criteria: A. After a trial of therapy (range 12-18 months) with Oxbryta (voxelotor) at 1500 mg per day (or the maximum tolerated dose for the member), if the members' hemoglobin does not improve by at least 1 gm/dl, Oxbryta (voxelotor) therapy should be discontinued.	Per Clinical Trial Analysis/Criteria