Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
			Remove inclusion criteria:	
			B.Non-Small Cell Lung Cancer (NSCLC)	
			2.NOTE: Per NCH Pathway & NCH Policy, [Bevacizumab + Carboplatin/Cisplatin +	
			Pemetrexed] followed by maintenance [Bevacizumab + Pemetrexed] is a non-Preferred	
			regimen. This recommendation is based on the lack of Level 1 Evidence (randomized	
			clinical trial and/or meta-analyses) to show superior outcomes compared to NCH	
			Preferred regimens for the initial treatment of NSCLC. Please refer to NCH Pathway for the	
UM ONC 1130	Alimta/Pemfexy (Pemetrexed)	Positive change	preferred treatments recommended for use in the above setting.	Per NCH Pathway expansion
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			Add inclusion criteria:	
			B.Non-Small Cell Lung Cancer (NSCLC)	
			3.NOTE 1: Per NCH Pathway & NCH Policy, the preferred drug is J9305 Alimta/generic	
			pemetrexed over J9304 Pemfexy for all lines of therapy in the treatment of NSCLC. This	
			recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or	
			meta-analyses) to show superior outcomes with Pemfexy over Alimta (pemetrexed) in the	
			treatment of NSCLC.	
			2.4.NOTE 2: Per NCH Pathway & NCH Policy, the following regimens are non-Preferred	
			based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses)	
			demonstrating superior outcomes compared to NCH Preferred regimens. Please refer to	
			NCH Pathway for the preferred treatments recommended for use in the first line	
			treatment of recurrent, advanced, or metastatic NSCLC:	
			a.Bevacizumab + Carboplatin/Cisplatin + Pemetrexed followed by maintenance	
			Bevacizumab + Pemetrexed	
			b.Nivolumab + Ipilimumab + Carboplatin/Cisplatin + Pemetrexed followed by	
			maintenance Nivolumab + Ipilimumab.	
			C.Malignant Pleural Mesothelioma	
			2.NOTE: Per NCH Pathway & NCH Policy, J9304 Pemfexy is a non-Preferred drug; the	
			preferred drug is J9305 Alimta (pemetrexed) for the treatment of malignant pleural	
			mesothelioma. This recommendation is based on the lack of Level 1 Evidence	
			(randomized clinical trial and/or meta-analyses) to show superior outcomes with Pemfexy	
UM ONC 1130	Alimta/Pemfexy (Pemetrexed)	Negative change	over Alimta (pemetrexed) in the treatment of malignant pleural mesothelioma.	Per NCH Pathway exclusion
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			Add inclusion criteria:	
			Clarified non-preferred note for all indications except Giant Cell Tumor of the bone:	
			2.NOTE: Per NCH Policy & NCH Pathway, Xgeva/Prolia (denosumab) are non-Preferred	
			drugs. The Preferred drugs are Zometa/Reclast (zoledronic acid) or Aredia (pamidronate);	
			this recommendation is based on the lack of Level 1 Evidence (randomized clinical trial	
			and/or meta-analyses) to show superior outcomes with Xgeva/Prolia (denosumab)	
			compared to Zometa/Reclast (zoledronic acid) or Aredia (pamidronate). Xgeva/Prolia	
			(denosumab) is an acceptable alternative for members with documented failure	
			/intolerance/contraindications to bisphosphonates, for example renal impairment and a	
UM ONC_1190	Bone Modifying Agents (Aredia, Zometa, Xgeva/Prolia)	Negative change	CrCl of < 30 mL/min.	Per NCH Pathway exclusion
-		-	Add inclusion criteria:	
			H.Esophageal Squamous Cell Carcinoma (ESCC)	
			a. The member has advanced, recurrent, or metastatic esophageal squamous cell	
			carcinoma (ESCC) AND	
			b.Opdivo (nivolumab) may be used in combination with Yervoy (ipilimumab) OR in	
			combination with fluoropyrimidine (e.g., fluorouracil or capecitabine) + platinum (e.g.,	
			cisplatin, carboplatin, or oxaliplatin) containing chemotherapy as first-line treatment,	
UM ONC_1201	Yervoy (ipilimumab)	Positive change	regardless of PD-L1 status.	New FDA Indication

UM ONC_1206 UM ONC 1221	Xalkori (crizotinib) Bosulif (bosutinib)	Positive change Negative change	Add inclusion criteria: C.Soft Tissue Sarcoma – Inflammatory Myofibroblastic Tumor (IMT) with ALK Translocation 1. Xalkori (crizotinib) may be used as a single agent for adult and pediatric members 1 year of age and older with inflammatory myofibroblastic tumor (IMT) with ALK translocation. Remove inclusion criteria: B.Chronic Myelogenous Leukemia (CML) Bosulif (bosutinib) is supported for use in all phases of Ph or BCR-ABL positive CML, including before and after hematopoietic cell transplantation OR in members with Y253H, E255K/V, F359C/I/V mutations.	New FDA Indication Per NCH Pathway exclusion
_			Add inclusion criteria: B.Chronic Myelogenous Leukemia (CML) 1.Bosulif (bosutinib) may be used in all phases of Philadelphia chromosome positive or BCR-ABL positive CML, including before and after hematopoietic stem cell transplantation, AND the member has a documented history of disease progression, contraindications, or intolerance to NCH preferred agents recommended for use in CML. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) demonstrating superior outcomes with one TKI over another except in members with the applicable BCR-ABL1 mutational analysis outlined below. 2.NOTE 2: After failure of first line therapy, the preferred options are Sprycel (dasatinib) (e.g., in members with F317L/Y/I/C, T315A, V299L mutations). Please refer to NCH policy UM ONC_1196 Sprycel (dasatinib) or UM ONC_1199 Tasigna (nilotinib), respectively. 3.NOTE 3: After failure of 2 prior Tyrosine Kinase Inhibitors (TKIs), the preferred agent is	
UM ONC_1221	Bosulif (bosutinib)	Negative change	Scemblix (asciminib). Please refer to NCH policy UM ONC_1455 Scemblix (asciminib) Add inclusion criteria: B.Methotrexate Toxicity 1.Voraxaze (glucarpidase) is being may be used in adult and pediatric members with ALL of the following conditions: a.Delayed methotrexate clearance due to renal impairment (i.e., creatinine clearance is 60 ml/min or less) b.Plasma concentration of methotrexate, 48 hours after start of Methotrexate, is > 1	Per NCH Pathway exclusion
UM ONC_1225	Voraxaze (glucarpidase)	Positive change	micromole per liter prior to the first dose of Voraxaze (glucarpidase). Add exclusion criteria: C.Treatment with Voraxaze (glucarpidase) exceeds the maximum duration limit of one dose (patients who received a second dose failed to achieve efficacy with the first dose,	Per FDA labeling
UM ONC_1225	Voraxaze (glucarpidase)	Negative change	this is supported per policy).	Per Clinical Trial Analysis/Criteria

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UM ONC_1228	Xtandi (enzalutamide)	Positive change	1.Non-Metastatic Castration Resistant Prostate Cancer (M0 disease with no visible metastases on conventional imaging AND a PSA Doubling Time of ≤ 10 months): 1.Xtandi (enzalutamide) may be used in this setting, in combination with an LHRH analog (ADT- Androgen Deprivation Therapy). 2.Xtandi (enzalutamide) may be used in this setting, in combination with an LHRH analog (ADT- Androgen Deprivation Therapy) Metastatic Castration Sensitive Prostate Cancer (M1 disease, castration-sensitive): 3.NOTE: Per NCH Policy & Pathway, the preferred Androgen Receptor Signaling Inhibitor, for metastatic castration-sensitive prostate cancer is generic abiraterone over Xtandi (enzalutamide) & Erleada (apalutamide), except when the member has experienced disease progression on generic abiraterone. Please refer to UM ONC_1208 for abiraterone policy. 4.Xtandi (enzalutamide) may be used in combination with an LH-RH analog (ADT-Androgen Deprivation Therapy) for members with castration-sensitive distant metastatic disease(M1, castration-sensitive) who experience disease progression on abiraterone, AND who have not been previously treated with Xtandi (enzalutamide) OR Erleada (apalutamide). 5.Metastatic Castration-Resistant Prostate Cancer: 6.NOTE: Per NCH Policy & Pathway, the preferred Androgen Receptor Signaling Inhibitor, for metastatic castration-resistant prostate cancer is generic abiraterone over Xtandi (enzalutamide) except when the member has experienced disease progression on generic abiraterone. Please refer to UM ONC_1208 for abiraterone policy. 7.2.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).	Per NCH Pathway expansion
UM ONC 1228	Xtandi (enzalutamide)	Positive change	Add inclusion criteria: B.Prostate Cancer 1.Xtandi (enzalutamide) may be used in combination with an LHRH analog or after orchiectomy (ADT- Androgen Deprivation Therapy) for ANY of the following clinical setting: a.In members with non-metastatic castration resistant prostate cancer, M0 disease with non visible metastases on conventional imaging, AND a PSA Doubling Time of ≤ 10 months OR b.In members with metastatic castration sensitive/resistant prostate cancer.	Per NCH Pathway expansion
UM ONC_1249	Mekinist (trametinib)	Positive change	Add inclusion criteria: E.Solid Tumors With BRAF V600E mutation (excluding colorectal cancer) 1.Mekinist (trametinib) may be used in combination with Tafinlar (dabrafenib) in adult or pediatric members ≥ 6 years of age with unresectable or metastatic solid tumors with BRAF V600E mutation, as subsequent therapy. The use of Mekinist (trametinib) in combination with Tafinlar (dabrafenib) in colorectal cancer is not supported per NCH Policy or NCH Pathway. This recommendation is based on the lack of response to a BRAF inhibitor in RAS wild type colorectal cancer. To overcome this resistance, the recommended alternative therapy for RAS wild type and BRAF V600E mutation positive recurrent/metastatic colorectal cancer is [Erbitux (cetuximab) + Braftovi (encorafenib)]; this is Preferred over triplet therapy with [Erbitux (cetuximab) + Braftovi (encorafenib)] + Mektovi (binimetinb)].	New FDA Indication
UM ONC 1249	Mekinist (trametinib)	Positive change	Add inclusion criteria: B. Malignant Melanoma a. Mekinist (trametinib) may be used as adjuvant treatment, following complete resection, in combination with Tafinlar (dabrafenib) for melanoma with BRAF V600E or V600K mutations.	Per FDA labeling
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			Add exclusion criteria:	1
			A.The member has BRAF wild-type melanoma, NSCLC, or anaplastic thyroid cancer	
			tumors. The use of Mekinist (trametinib) + Tafinlar (dabrafenib) in colorectal cancer is	
UM ONC 1249	Mekinist (trametinib)	Negative change	not supported per NCH policy and NCH pathway.	Per FDA labeling
OW ONC_1249	Wekinst (transetinib)	ivegative change	not supported per Nert policy and Nert patriway.	Fel i DA labelling
			Add inclusion criteria:	
			E.Solid Tumors With BRAF V600E mutation (excluding colorectal cancer)	
			Mekinist (trametinib) may be used in combination with Tafinlar (dabrafenib) in adult or	
			pediatric members ≥ 6 years of age with unresectable or metastatic solid tumors with	
			BRAF V600E mutation, as subsequent therapy. The use of Mekinist (trametinib) in	
			combination with Tafinlar (dabrafenib) in colorectal cancer is not supported per NCH	
			Policy or NCH Pathway. This recommendation is based on the lack of response to a BRAF	
			inhibitor in RAS wild type colorectal cancer. To overcome this resistance, the	
			The state of the s	
			recommended alternative therapy for RAS wild type and BRAF V600E mutation positive	
			recurrent/metastatic colorectal cancer is [Erbitux (cetuximab) + Braftovi (encorafenib)];	
	T C L (LL C 11)	- ··· ·	this is Preferred over triplet therapy with [Erbitux (cetuximab) + Braftovi (encorafenib)] +	
UM ONC_1250	Tafinlar (dabrafenib)	Positive change	Mektovi (binimetinb)].	New FDA Indication
			Add inclusion criteria:	
			B.BRAF V600E or V600K mutation positive Melanoma	
			a.Tafinlar (dabrafenib) may be used in combination with Mekinist (trametinib) as	
			adjuvant treatment, following complete resection, for melanoma with BRAF V600E or	
UM ONC_1250	Tafinlar (dabrafenib)	Positive change	V600K mutations.	Per FDA labeling
			Add exclusion criteria:	
			A.The member has wild-type BRAF tumors melanoma, NSCLC, anaplastic/non-anaplastic	
			(all other histologies included) thyroid carcinoma. The use of Tafinlar (dabrafenib) +	
			Mekinist (trametinib) in colorectal cancer is not supported per NCH policy and NCH	
			pathway.	
			D.C.Treatment exceeds the maximum limit of 18 90 (50 mg) tablets/month or 60 (75 mg)	
UM ONC_1250	Tafinlar (dabrafenib)	Negative change	tablets/month.	Per FDA labeling
UM ONC_1261	Cyramza (ramucirumab)	No Clinical Changes	N/A	N/A
			Remove inclusion criteria:	
			B.Acute Lymphoblastic Leukemia (ALL) (Both Philadelphia chromosome positive and	
			negative subtypes)	
			6.NOTE: NCH Pathway Preferred Regimen for MRD+ (measurable residual disease or	
			minimal residual disease)/relapsed/refractory CD19 positive B-cell ALL is Blincyto	
			(blinatumomab) over salvage chemotherapy and over Besponsa (inotuzumab ozogamicin).	
			This recommendation is based on the trials that led to the approval of Blincyto	
			(blinatumomab) which demonstrated improvements in OS and rates of remission in both	
			Ph positive and negative ALL when compared to standard chemotherapy. Furthermore,	
			there is no Level 1 evidence (randomized trials and or meta-analyses) to show that	
			Besponsa (Inotuzumab Ozogamicin) is superior in terms of efficacy over Blincyto.	
			Besponsa (Inotuzumab Ozogamicin) is superior in terms of efficacy over Blincyto. 7. Blincyto (blinatumomab) may be used as a single agent for members with	
UM ONC_1270	Blincyto (blinatumomab)	Positive change	Besponsa (Inotuzumab Ozogamicin) is superior in terms of efficacy over Blincyto.	Per NCH Pathway expansion
UM ONC_1270	Blincyto (blinatumomab)	Positive change	Besponsa (Inotuzumab Ozogamicin) is superior in terms of efficacy over Blincyto. 7.Blincyto (blinatumomab) may be used as a single agent for members with relapsed/refractory CD19 positive B-cell ALL	Per NCH Pathway expansion
UM ONC_1270	Blincyto (blinatumomab)	Positive change	Besponsa (Inotuzumab Ozogamicin) is superior in terms of efficacy over Blincyto. 7.Blincyto (blinatumomab) may be used as a single agent for members with relapsed/refractory CD19 positive B-cell ALL Add inclusion criteria:	Per NCH Pathway expansion
UM ONC_1270	Blincyto (blinatumomab)	Positive change	Besponsa (Inotuzumab Ozogamicin) is superior in terms of efficacy over Blincyto. 7.Blincyto (blinatumomab) may be used as a single agent for members with relapsed/refractory CD19 positive B-cell ALL	Per NCH Pathway expansion
UM ONC_1270	Blincyto (blinatumomab)	Positive change	Besponsa (Inotuzumab Ozogamicin) is superior in terms of efficacy over Blincyto. 7. Blincyto (blinatumomab) may be used as a single agent for members with relapsed/refractory CD19 positive B-cell ALL Add inclusion criteria: B. Acute Lymphoblastic Leukemia (ALL) (Both Philadelphia chromosome positive and negative subtypes)	Per NCH Pathway expansion
UM ONC_1270	Blincyto (blinatumomab)	Positive change	Besponsa (Inotuzumab Ozogamicin) is superior in terms of efficacy over Blincyto. 7.Blincyto (blinatumomab) may be used as a single agent for members with relapsed/refractory CD19 positive B-cell ALL Add inclusion criteria: B.Acute Lymphoblastic Leukemia (ALL) (Both Philadelphia chromosome positive and	Per NCH Pathway expansion
UM ONC_1270	Blincyto (blinatumomab)	Positive change	Besponsa (Inotuzumab Ozogamicin) is superior in terms of efficacy over Blincyto. 7. Blincyto (blinatumomab) may be used as a single agent for members with relapsed/refractory CD19 positive B-cell ALL Add inclusion criteria: B. Acute Lymphoblastic Leukemia (ALL) (Both Philadelphia chromosome positive and negative subtypes)	Per NCH Pathway expansion
UM ONC_1270	Blincyto (blinatumomab)	Positive change	Besponsa (Inotuzumab Ozogamicin) is superior in terms of efficacy over Blincyto. 7.Blincyto (blinatumomab) may be used as a single agent for members with relapsed/refractory CD19 positive B-cell ALL Add inclusion criteria: B.Acute Lymphoblastic Leukemia (ALL) (Both Philadelphia chromosome positive and negative subtypes) 7.Blincyto (blinatumomab) may be used as a single agent for members with	Per NCH Pathway expansion
UM ONC_1270	Blincyto (blinatumomab)	Positive change	Besponsa (Inotuzumab Ozogamicin) is superior in terms of efficacy over Blincyto. 7.Blincyto (blinatumomab) may be used as a single agent for members with relapsed/refractory CD19 positive B-cell ALL Add inclusion criteria: B.Acute Lymphoblastic Leukemia (ALL) (Both Philadelphia chromosome positive and negative subtypes) 7.Blincyto (blinatumomab) may be used as a single agent for members with relapsed/refractory CD19 positive B-cell ALL OR	Per NCH Pathway expansion
UM ONC_1270	Blincyto (blinatumomab)	Positive change	Besponsa (Inotuzumab Ozogamicin) is superior in terms of efficacy over Blincyto. 7. Blincyto (blinatumomab) may be used as a single agent for members with relapsed/refractory CD19 positive B-cell ALL Add inclusion criteria: B. Acute Lymphoblastic Leukemia (ALL) (Both Philadelphia chromosome positive and negative subtypes) 7. Blincyto (blinatumomab) may be used as a single agent for members with relapsed/refractory CD19 positive B-cell ALL OR 1. Blincyto (blinatumomab) may be used as a single agent as consolidation therapy for	Per NCH Pathway expansion
UM ONC_1270	Blincyto (blinatumomab)	Positive change	Besponsa (Inotuzumab Ozogamicin) is superior in terms of efficacy over Blincyto. 7. Blincyto (blinatumomab) may be used as a single agent for members with relapsed/refractory CD19 positive B-cell ALL Add inclusion criteria: B.Acute Lymphoblastic Leukemia (ALL) (Both Philadelphia chromosome positive and negative subtypes) 7. Blincyto (blinatumomab) may be used as a single agent for members with relapsed/refractory CD19 positive B-cell ALL OR 1. Blincyto (blinatumomab) may be used as a single agent as consolidation therapy for members with CD 19 positive B- cell ALL that is minimal residual disease positive (MRD+)	Per NCH Pathway expansion

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UM ONC_1270 UM ONC_1271	Blincyto (blinatumomab) Farydak (panobinostat)	Negative change N/A	Add inclusion criteria: B.Acute Lymphoblastic Leukemia (ALL) (Both Philadelphia chromosome positive and negative subtypes) NOTE: Per NCH Pathway & NCH Policy, Blincyto (blinatumomab) ± TKI (e.g., imatinib, dasatinib, nilotinib, ponatinib, bosutinib) is a non-Preferred regimen for induction/consolidation treatment of Philadelphia Chromosome Positive B cell ALL. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with Blincyto (blinatumomab) ± TKI compared to standard induction/consolidation chemotherapy +/- TKI. Please refer to NCH Pathway for the preferred treatments recommended for use in ALL. N/A Add inclusion criteria:	Per NCH Pathway exclusion Archive policy: FDA withdrew from the market or
UM ONC_1272	lbrance (palbocidib)	Positive change	B.Breast Cancer 1.Ibrance (palbociclib) may be used in members with ER/PR positive and HER2 negative recurrent or metastatic breast cancer as follows: a.In combination with an aromatase inhibitor [i.e., Arimidex (anastrozole), Femara (letrozole), Aromasin (exemestane)], (in postmenopausal/premenopausal women treated with ovarian oblation/suppression women)	Per Compendia Listing
UM ONC_1274	Opdivo (nivolumab)	Positive change	Add inclusion criteria: I.Esophageal Carcinoma 1.Squamous Cell Carcinoma of Esophagus a.The member has advanced, recurrent, or metastatic esophageal squamous cell carcinoma (ESCC), regardless of PD-L1 status AND i. Opdivo (nivolumab) may be used as monotherapy in a member who has experienced disease progression on or after prior fluoropyrimidine based chemotherapy (e.g., fluorouracil or capecitabine) and platinum-based chemotherapy (e.g., cisplatin, carboplatin, or oxaliplatin) AND OR i.ii. Opdivo (nivolumab) may be used in combination with Yervoy (ipilimumab) OR in combination with fluoropyrimidine (e.g., fluorouracil or capecitabine) + platinum (e.g., cisplatin, carboplatin, or oxaliplatin) containing chemotherapy as first-line treatment.	New FDA Indication
_			Add inclusion criteria: B.Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) 1.Venclexta (venetoclax) may be used in combination with Gazyva (obinutuzumab) as first line therapy OR as a single agent with or without rituximab/rituximab biosimilar	
UM ONC_1297	Venclexta (venetoclax)	Positive change	product as first or subsequent line therapy for the treatment of CLL/SLL. Remove inclusion criteria: 2. Venclexta (venetoclax) may be used with Imbruvica (ibrutinib) in members with CLL and any one of the following: age 65 years or greater, del(17p), del(11q), TP53 mutation, unmutated IGHV (immunoglobulin heavy chain).	Per Compendia Listing
UM ONC_1297	Venclexta (venetoclax) Venclexta (venetoclax)	Negative change Negative change	Add inclusion criteria: E.Acute Lymphoblastic Leukemia (ALL) 2.1. NOTE: Per NCH Pathway & NCH Policy, Venclexta (venetoclax) + Chemotherapy (e.g., decitabine, hyper-CVAD, nelarabine, mini-hyper-CVD) is a non-Preferred regimen for the treatment of relapsed/refractory ALL. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with Venclexta (venetoclax) + Chemotherapy compared to NCH Preferred regimens. Please refer to NCH Pathway for the preferred treatments recommended for use in relapsed/refractory ALL.	Per FDA labeling Per NCH Pathway exclusion

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			Remove exclusion criteria:	
			D.Treatment exceeds the maximum months duration limit of 12 months when used in	
			combination with Gazyva (obinutuzumab) or with Imbruvica (ibrutinib) for the treatment	
			of CLL (unless the the member is MRD+ at the end of 12 months). Venclexta (venetoclax) +	
UM ONC_1297	Venclexta (venetoclax)	Positive change		Per FDA labeling
			Add inclusion criteria:	
			B.Breast Cancer	
			b.Member is postmenopausal OR if member is premenopausal, the member is also	
UM ONC_1310	Kisqal (ribociclib)	Positive change	receiving ovarian ablation/suppression, e.g., with leuprolide.	Per Compendia Listing
			Add exclusion criteria:	
UM ONC_1310	Kisqal (ribociclib)	Negative change	D.Treatment exceeds the maximum limit of 99 63 (200 mg) tablets/month.	Per FDA labeling
			Add inclusion criteria:	
			B.Acute Myeloid Leukemia (AML)	
			1. The member has CD33-positive AML and Mylotarg (gemtuzumab ozogamicin) is being	
			used as a single agent OR in combination with chemotherapy for members with newly	
			diagnosed AML (age 1 month and older)/relapsed/refractory AML (age 2 years and older)	
UM ONC_1325	Mylotarg (gemtuzumab ozogamicin)	Positive change	who have not received Mylotarg previously.	Per FDA labeling
			Add inclusion criteria:	
			2.NOTE: Per NCH Pathway & NCH Policy, the following regimens are Non-Preferred ba	
			sed on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to	
			show superior outcomes compared to NCH Preferred regimens. Please refer to NCH	
			Pathway for the preferred alternative regimens for the following:	
			a.Induction therapy, <60 years of age: Fludarabine + HiDAC + idarubicin + G-CSF +	
			gemtuzumab ozogamicin	
			b.Induction/Consolidation therapy, ≥ 60 years of age: Single agent Mylotarg	
UM ONC_1325	Mylotarg (gemtuzumab ozogamicin)	Negative change	(gemtuzumab ozogamicin).	Per NCH Pathway exclusion
			Remove exclusion criteria:	
UM ONC_1325	Mylotarg (gemtuzumab ozogamicin)	Positive change	A.Lack of confirmation that the AML cells are CD-33 +	Per Clinical Trial Analysis/Criteria
			Add inclusion criteria:	
			B.Acute Myeloid Leukemia (AML)	
		1	1. Vyxeos (daunorubicin and cytarabine liposomal) may be used for induction and	
			consolidation therapy for adult members aged 60 years or older, who have newly	
			diagnosed, therapy-related AML or AML with MDS-associated cytogenetic abnormalities.	
		1	NOTE: Per NCH Pathway & NCH Policy, Vyxeos (daunorubicin and cytarabine liposomal) is	
			non-Preferred as induction treatment in adult members aged 60 years or older with newly	
			diagnosed AML, except for members with therapy-related AML or AML with MDS-	
			associated cytogenetic abnormalities. The preferred induction treatment for the above	
			clinical setting is cytarabine + daunorubicin/idarubicin. This recommendation is based on	
		1	the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show	
			superior outcomes with Vyxeos (daunorubicin and cytarabine liposomal) compared to	
UM ONC 1326	Vyxeos (daunorubicin and cytarabine liposomal)	Negative change	cytarabine + daunorubicin/idarubicin as induction treatment in newly diagnosed AML.	Per NCH Pathway exclusion
OIVI OINC_1320	vyxeos (uaumorubiciii anu cytarabine nposomai)	ivegative triange	1	rei Neitratiiway exclusion
			Add inclusion criteria:	
			B.Acute Myeloid Leukemia (AML)	
			2. Vyxeos (daunorubicin and cytarabine liposomal) may be used for induction and	
		1	consolidation therapy for pediatric members 1-17 years of age, who have therapy-related	
UM ONC_1326	Vyxeos (daunorubicin and cytarabine liposomal)	Positive change	AML or AML with MDS-associated cytogenetic abnormalities.	Per FDA labeling

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			Add inclusion criteria:	
			B.Breast Cancer	
			b. The member is postmenopausal OR is premenopausal treated with ovarian	
			oblation/suppression (e.g. LHRH agonist) AND Verzenio (abemaciclib) will be used for any	
			of the following criteria:	
			i.In combination with an aromatase inhibitor as first line therapy OR	
			ii.In combination with fulvestrant as first line or subsequent therapy OR	
			iii. As a single agent for disease progression following endocrine therapy (that did not	
UM ONC 1328	Verzenio (abemaciclib)	Positive change	include a CDK4/6 inhibitor) AND chemotherapy for metastatic disease.	Per FDA labeling
OIVI OINC_1328	verzenio (abeniaciciib)	Positive change	Include a CDK4/6 Inhibitor) AND chemotherapy for metastatic disease.	Per FDA labelling
			Add inclusion criteria:	
			B.Prostate Cancer	
			1.Erleada (apalutamide)may be used in combination with an LHRH analog or after	
			orchiectomy (ADT- Androgen Deprivation Therapy) for ANY of the following clinical setting:	
			a.In members with non-metastatic castration resistant prostate cancer, M0 disease with	
			no visible metastases on conventional imaging, AND a PSA Doubling Time of ≤ 10 months	
			OR	
UM ONC_1333	Erleada (apalutamide)	Positive change	b.In members with metastatic castration sensitive prostate cancer.	Per Compendia Listing
			Remove inclusion criteria:	
		1	B.Prostate Cancer	
			1.Non-Metastatic Castration Resistant Prostate Cancer (M0 disease with no visible	
			metastases on conventional imaging AND a PSA Doubling Time of ≤ 10 months):	
			a.Erleada (apalutamide) may be used in this setting, in combination with an LH-RH	
			analog (ADT- Androgen Deprivation Therapy).	
			2.Metastatic Castration-Sensitive Prostate Cancer (M1 disease, castration-sensitive):	
			NOTE: Per NCH Policy & Pathway, the preferred Androgen Receptor Signaling Inhibitor, for	
			metastatic castration-sensitive prostate cancer is generic abiraterone over Xtandi	
			(enzalutamide) & Erleada (apalutamide). Please refer to UM ONC_1208 for abiraterone	
			policy.	
			a.Erleada (apalutamide) may be used in combination with an LH-RH analog (ADT-	
			Androgen Deprivation Therapy) for members with castration-sensitive distant metastatic	
			disease (M1, castration-sensitive) who experienced disease progression on abiraterone,	
			AND who have not been previously treated with Xtandi (enzalutamide) OR Erleada	
UM ONC_1333	Erleada (apalutamide)	Positive change	(apalutamide).	Per NCH Pathway expansion
			Add inclusion criteria:	
		1	B.Non-Small Cell Lung Cancer (NSCLC)	
		1	2. Vizimpro (dacomitinib) may be used as monotherapy as first line therapy for the	
			treatment of advanced/recurrent/metastatic NSCLC with EGFR exon 19 deletion or the	
UM ONC_1341	Vizimpro (dacomitinib)	Positive change	L858R mutation in exon 21 as detected by an FDA approved test.	Per FDA labeling
			Remove inclusion criteria:	
		1	B.Non-Small Cell Lung Cancer (NSCLC)	
			2. Vizimpro (dacomitinib) may be used in EGFR + metastatic/advanced/recurrent NSCLC if:	
		1	a.The member has advanced or metastatic NSCLC and the presence of EGFR activating	
		1	mutations with exon 19 deletion or the L858R mutation in exon 21 as detected by an FDA	
		1	approved test AND	
			1 ''	
		1	b.Vizimpro (dacomitinib) will be used as a single agent AND	
		1	c.If being used as first line therapy, use would be restricted to members with	
		1	intolerance/contraindications to Tagrisso (osimertinib) OR	
		1	d.If being used as subsequent therapy, the member has experienced disease progression	
		1	on chemotherapy AND/OR on another tyrosine kinase inhibitor [e.g., Tarceva (erlotinib),	
UM ONC_1341	Vizimpro (dacomitinib)	Negative change	Gilotrif (afatinib), Iressa (gefitinib), or Tagrisso (osimertinib)].	Per Compendia Listing
			Add exclusion criteria:	
UM ONC_1341	Vizimpro (dacomitinib)	Negative change	A.Disease progression on prior treatment with Tagrisso (osimertinib).	Per Clinical Trial Analysis/Criteria
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			Add inclusion criteria:	
			B.Hairy Cell Leukemia	
			1.The member has relapsed/refractory hairy cell leukemia that is positive for CD22 on	
UM ONC_1348	Lumoxiti (moxetumomab pasudotox)	Negative change	any standard test	Per FDA labeling
			Add inclusion criteria:	
			B.Prostate Cancer	
			b.Nubeqa (darolutamide) will be used in combination with an LHRH analog or following	
UM ONC_1363	Nubeqa (darolutamide)	Positive change	orchiectomy (ADT- Androgen Deprivation Therapy).	Per Compendia Listing
UM ONC_1411	Blenrep (belantamab mafodotin-blmf)	No Clinical Changes	N/A	N/A
			Addinaturing arthuring	
			Add inclusion criteria:	
			B.Upper Tract Urothelial Carcinoma (UTUC)	
			1.The member has non-metastatic, low-grade, upper tract urothelial cancer AND	
			2.Jelmyto (mitomycin for pyelocalyceal instillation) may be used as a single agent	
			following endoscopic resection or ablation or in members who are not candidates for	
			endoscopic/surgical intervention as primary treatment or for treatment of recurrent	
UM ONC_1415	Jelmyto (mitomycin for pyelocalyceal installation)	Positive change	disease.	Per FDA labeling
UM ONC_1423	Ukoniq (umbralisib)	N/A	N/A	Communication
UM ONC_1443	Mozobil (plerixafor)	No Clinical Changes	N/A	N/A
		1	B.Basal Cell Carcinoma (BCC)	
			d.Photofrin (porfimer sodium): for use as photodynamic therapy for superficial BCC.	
			C.Cutaneous Squamous Cell Carcinoma (cSCC)	
			a.Picato (ingenol mebutate): for use as topical therapy for actinic keratoses.	
			c.Photofrin (porfimer sodium): for use as photodynamic therapy for actinic keratoses OR	
			for cSCC in situ (Bowen's disease).	
			d.Lactic acid/Salicylic acid: use as topical therapy for pre-treatment of hyperkeratotic	
			actinic keratoses.	
			e.Tazorac (tazarotene): use as topical therapy for pre-treatment of hyperkeratotic actinic	
			keratoses.	
			f.Urea: use as topical therapy for pre-treatment of hyperkeratotic actinic keratoses.	
			D.Primary Cutaneous Lymphomas	
			E.NOTE: Per NCH policy, Tazorac (topical tazarotene) Valchlor (topical mechlorethamine)	
			is the preferred treatment option over Targretin (topical bexarotene) other-	
			topical/intralesional therapies (e.g., Targretin, Valchlor, Aldara, Clobestasol, Kenalog,	
			Rituxan) for the treatment of primary cutaneous lymphomas. This recommendation is	
			based on the lack of level 1 evidence (randomized trial and/or meta-analysis) to show	
			superior outcomes over Tazorac (topical tazarotene), with Targretin (topical bexarotene)	
			over Valchlor (topical mechlorethamine).	
			a.For members with primary cutaneous T-cell lymphoma (including mycosis fungoides,	
			Sezary syndrome, primary cutaneous CD30+ T-cell lymphoproliferative disorders):	
		1	iii.Tazorac (topical tazarotene)	
		1	iv.Aldara (topical imiquimod)	
1		1	b.For members with primary cutaneous B-cell lymphoma (including marginal zone or	
			follicle center lymphoma):	
			iii.Aldara (topical imiguimod)	
UM ONC 1445	Topical and Intralesional Therapies	Negative change	iv.Clobetasol propionate (topical corticosteroid)	Per FDA labeling
OIVI OIVC_1443	Topical and intralesional frierapies	INCEGUIVE CHANGE	Remove exclusion criteria:	I G I DV INDEILIE
		1	B.Dosing exceeds the available topical package size per single treatment: Levulan	
		1	Kerastick 20% solution (1 applicator), Carac 0.5% cream (30 gm), Efudex 5% cream (40	
			gm), Fluoroplex 1% cream (30 gm), Aldara 5% cream (12 pack), Picato 0.05% gel (2	
			tubes), Targretin 1% gel (60 gm), and Valchlor 0.016% gel (60 gm), and Tazorac 0.05% or	
			0.1% cream/get (30/60/100 gm), and Valentior 0.016% get (60 gm), and razorae 0.05% or	
UM ONC 1445	Topical and Intralesional Therapies	Positive change	(15/30/45/60 cm).	Per FDA labeling
OIVI OINC_1443	Topical and intralesional Therapies	Positive change	Add exclusion criteria:	Let I Dy tanelling
UM ONC 1446	Welireg (belzutifan)	Negative change	B.The member has metastatic disease.	Per FDA labeling
01VI 01VC_1440	יייבוויפה (מכובענוומוו)	regative change	D. The member has incressed uiscase.	I CI I DA IGUEITING
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