Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes	Post UMC comments
NEW	Scemblix (asciminib)	n/a	n/a	n/a	
NEW	Besremi (ropeginterferon alfa-2b-njft)	n/a	n/a	n/a	
UM ONC_1028	Avastin (bevacizumab)/Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr)	Positive change	Remove inclusion criteria: B. Colorectal Cancer b.As subsequent therapy after progression on a prior non-bevacizumab based regimen, given in combination with FOLFOX, FOLFIRI, XELIRI, and XELOX/CapeOX. c.Bevacizumab may be used in a maximum of 2 lines of therapy, in the metastatic setting.	Other: see below for clarity	
UM ONC_1028	Avastin (bevacizumab)/Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr)	Negative change	Add inclusion criteria: B.Colorectal Cancer b. As subsequent line therapy given in combination with FOLFOX, FOLFIRI, XELIRI, and XELOX/CapeOX. Bevacizumab may be used up to 2 lines of therapy after progression on a bevacizumab containing regimen in the metastatic setting. F. Cervical Cancer 1.NOTE: Avastin (bevacizumab)/Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr) + Cisplatin/Carboplatin + Paclitaxel is the preferred regimen for initial/first line therapy for metastatic cervical carcinoma. 2.The member has cervical cancer and Avastin (bevacizumab)/Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr) is being used as first line therapy in combination with (paclitaxel and cisplatin/carboplatin +/- pembrolizumab if PD-L1 ≥ 1) or topotecan for local/regional recurrence or distant metastases.	Per Clinical Trial Analysis/Criteria	
UM ONC_1134	Trastuzumab Products, Pertuzumab (pertuzumab), and Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf)	Positive change	Remove inclusion criteria: B.HER-2 Positive Breast Cancer 1.Herceptin (trastuzumab), Herceptin Hylecta (trastuzumab hyaluronidase), Ogivri (trastuzumab-dkst), Herzuma (trastuzumab-pkrb), Ontruzant (trastuzumab-dttb), Kanjinti, or Trazimera (trastuzumab-qyyp) is being used as ONE of the following: a.In combination with chemotherapy with or without Perjeta (pertuzumab) for neoadjuvant or adjuvant therapy as follows: i.In the neoadjuvant (pre-operative) setting, trastuzumab may be used with or without Perjeta (pertuzumab). ii.Trastuzumab may be used with Perjeta (pertuzumab), in the neoadjuvant setting, in combination with chemotherapy, for stage II OR node positive disease. iii.Trastuzumab + Perjeta (pertuzumab) use in the adjuvant (post-operative) setting is restricted in members who did not receive neoadjuvant therapy, OR, received neoadjuvant therapy and did not have any residual disease in the breast and/or axillary lymph nodes at surgery. iv.NOTE: If neoadjuvant therapy was given, and there is evidence of residual disease in the breast and or axillary nodes, then the Preferred drug per NCH Policy & NCH Pathway is Kadcyla (ado-trastuzumab). b.Trastuzumab may be used in combination with any of the following neoadjuvant or adjuvant regimens: i.Paclitaxel +/- pertuzumab following AC (doxorubicin and cyclophosphamide) ii.Docetaxel +/- pertuzumab following AC (doxorubicin and cyclophosphamide) iii.In TCH (docetaxel, carboplatin, and trastuzumab) +/- pertuzumab iv.In combination with docetaxel and cyclophosphamide.	Other: see below for clarity	

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UM ONC_1134	Trastuzumab Products, Pertuzumab (pertuzumab), and Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf)	Negative change	Add inclusion criteria: NOTE 1: For neoadjuvant therapy, Pertuzumab is only indicated in members with node positive or ER/PR negative disease. NOTE 2: For adjuvant therapy, Trastuzumab + Pertuzumab are indicated in members with stage II or III disease. If there is evidence of residual disease in the breast and or axillary nodes at surgery, then the Preferred drug per NCH Policy & NCH Pathway for adjuvant therapy is Kadcyla (ado-trastuzumab). NOTE 3: Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf) may be used anywhere Trastuzumab + Pertuzumab containing therapy is indicated. a.Trastuzumab +/- Pertuzumab may be used as neoadjuvant treatment OR as adjuvant treatment in members who did not receive neaodjuvant therapy or in members who received neoadjuvant therapy and did not have any residual disease in the breast or axillary lymph nodes at surgery. The following regimens are acceptable for use with Trastuzumab +/- Pertuzumab combination therapy: i.Trastuzumab +/- Pertuzumab with Paclitaxel following AC ii.Trastuzumab +/- Pertuzumab with Docetaxel following AC iii.Trastuzumab +/- Pertuzumab with Docetaxel/ Paclitaxel iv.TCH (docetaxel, carboplatin, and trastuzumab) +/- pertuzumab v.Trastuzumab with Docetaxel and Cyclophosphamide. b.Trastuzumab +/- Pertuzumab may be use as continuation adjuvant therapy following adjuvant Trastuzumab +/- Pertuzumab + Chemotherapy.	Per Clinical Trial Analysis/Criteria	
UM ONC_1190	Bone Modifying Agents (Aredia, Zometa, Xgeva/Prolia)	Positive change	Add inclusion criteria: H.Giant Cell Tumor of Bone 1.The member is an adult or adolescent 12 years of age or older with giant cell tumor of the bone and Xgeva (denosumab) is being will be used as a single agent ~~or combined with interferon alfa/peginterferon or radiation therapy~~ for unresectable localized disease OR ~~as a single agent~~ for metastatic disease.	Per FDA labeling	
UM ONC_1215	Treanda/Bendeka/Belrapzo (bendamustine)	Negative change	Add inclusion criteria: Add preferred Truxima and Ruxience when used in combination with bendamustine products for the following indications: B.Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma C.Non-Hodgkin's Lymphoma	More Cost Effective Alternative(s)	
UM ONC_1215	Treanda/Bendeka/Belrapzo (bendamustine)	Negative change	Add exclusion criteria: B.Dosing exceeds single dose limit of Treanda/Bendeka/Belrapzo (bendamustine) 100 mg/m2 for CLL; 120 mg/m2 for NHL.	Per FDA labeling	
UM ONC_1219	Jevtana (cabazitaxel)	Negative change	Add inclusion criteria: B.Prostate Cancer 1.NOTE: The preferred dose of Jevtana for NCH Policy is 20 mg/m2 IV every 3 weeks. This dose is associated with a ~~LOW~~ lower risk for febrile neutropenia and clinically significant ADRs than 25 mg/m2 IV every 3 weeks. 2.The member has evidence of castration-resistant distant metastatic (M1) disease, no visceral metastases, and has experienced disease progression on docetaxel therapy AND. 3.Jevtana (cabazitaxel) will be given with concurrent steroid and androgen deprivation therapy (ADT).	Per Clinical Trial Analysis/Criteria	
UM ONC_1219	Jevtana (cabazitaxel)	Negative change	Add exclusion criteria: A.Use of Jevtana (cabazitaxel) in members with disease progression on all of the following: Taxotere (docetaxel), Zytiga (abiraterone), AND Erleada (apalutamide)/Xtandi (enzalutamide). Use of Jevtana (cabazitaxel) did not improve clinical outcomes in patients with disease progression or is refractory to docetaxel and to prior androgen-signaling-targeted agents, abiraterone followed by enzalutamide or vice versa. A.B.Dosing exceeds single dose limit of Jevtana (cabazitaxel) ~~20~~ 25 mg/m2.	Per Clinical Trial Analysis/Criteria	
UM ONC_1222	Erivedge (vismodegib)	No Clinical Changes	N/A	N/A	

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UM ONC_1223	Inlyta (axitinib)	Negative change	Add inclusion criteria: B.Renal Cell Carcinoma (RCC) 3.Inlyta (axitinib) may be used as a single agent after failure of one prior systemic therapy in members with relapsed, medically unresectable, advanced, or metastatic renal cell carcinoma and Inlyta (axitinib) ~~is being used in the second or later line of therapy.~~	Per FDA labeling	
UM ONC_1227	Zolinza (vorinostat)	Negative change	Add inclusion criteria: B.Cutaneous T-Cell Lymphoma (CTCL) 1.The member has relapsed/refractory stage IIB-IV CTCL (including mycosis fungoides or Sezary syndrome) AND Zolinza (vorinostat) will be used as monotherapy. ~~2.Zolinza (vorinostat) is being used as a single agent AND~~ ~~3.The member has experienced disease progression on two prior systemic therapies.~~	Per FDA labeling	
UM ONC_1230	Istodax (romidepsin)	Negative change	Add inclusion criteria: B.Cutaneous T-Cell Lymphomas (CTCL) 1.The member has relapsed/refractory stage IIB-IV CTCL (including mycosis fungoides or Sezary syndrome) and Istodax (romidepsin) is being used as monotherapy. ~~AND~~ ~~2.Istodax (romidepsin) is being used as a single agent AND~~ ~~3.The member has experienced disease progression on one prior systemic therapy.~~	Per FDA labeling	
UM ONC_1231	Marqibo (vincristine liposome)	No Clinical Changes	N/A	N/A	
UM ONC_1233	Tykerb (lapatinib)	No Clinical Changes	N/A	N/A	
UM ONC_1263	Keytruda (pembrolizumab)	Positive change	Add inclusion criteria: I.Cervical Cancer 1.The member has recurrent or metastatic microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) cervical cancer or PD-L1 positive, CPS or TPS ≥ 1%, tumors AND 2. Keytruda (pembrolizumab) will be used in combination with chemotherapy, with or without Avastin (bevacizumab), as first line systemic therapy in members with recurrent or non-metastatic cervical cancer who are refractory to or not a candidate for surgery and/or radiation OR 3.Keytruda (pembrolizumab) will be used as a single agent as subsequent therapy following disease progression on or after prior chemotherapy treatment, with no exposure to prior Keytruda (pembrolizumab).	New FDA Indication	
UM ONC_1263	Keytruda (pembrolizumab)	Negative change	Add inclusion criteria: L.Renal Cell Carcinoma (RCC) 5.Keytruda (pembrolizumab) may be used as a single agent adjuvant therapy in resected renal cell carcinoma that is positive for PD-L1 ≥1 and if any ONE of the following criteria are met: a.Stage II disease with grade 4 histology or with sarcomatoid differentiation b.Stage III or higher disease c.Regional nodal metastases d.M1 NED: Member with resectable metastases at diagnosis and surgical resection of the primary and of the metastatic lesions (within 1 year of nephrectomy) and No Evidence Of Metastatic disease prior to starting Keytruda (pembrolizumab).	New FDA Indication	
UM ONC_1265	Zykadia (ceritinib)	Negative change	Add exclusion criteria: C.Treatment exceeds the maximum limit of ~~150~~90 (150 mg) capsules/tablets per month.	Per FDA labeling	

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UM ONC_1280	Darzalex and Darzalex Faspro (daratumumab)	Negative change	Add inclusion criteria: B.Multiple Myeloma 4.Daratumumab may be used in members with relapsed/refractory multiple myeloma as a part of the following regimens: •Daratumumab + Pomalidomide + Steroid (DRd) if the member has failed 1-2 prior regimens or line of therapies that include one proteasome inhibitor (e.g., bortezomib, ixazomib, carfilzomib) & one immunomodulatory agent (e.g.,lenalidomide, thalidomide) OR •Daratumumab + Lenalidomide + Steroid (DRd) OR •Daratumumab + Bortezomib + Steroid (DVd) •As a single agent if the member has failed at least 2-3 prior lines of therapy including one proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib) & one immunomodulatory agent (e.g., lenalidomide, pomalidomide, thalidomide).	Per FDA labeling	
UM ONC_1281	Empliciti (elotuzumab)	Negative change	Add inclusion criteria: B.Multiple Myeloma 1.Empliciti (elotuzumab) may be used in ~~combination with Pomalyst (pomalidomide) with/without dexamethasone in~~ members with relapsed/refractory multiple myeloma that have in the following combination therapy: a.In combination with Revlimid (lenalidomide) with or without dexamethasone in members who have received 1-3 prior therapies OR b.In combination with Pomalyst (pomalidomide) with or without dexamethasone in members who have received at least 2 prior regimens including and immunomodulatory agent specifically Revlimid (unless intolerance/contraindication) and a proteasome inhibitor specifically Velcade (unless intolerance/contraindication).	Per FDA labeling	
UM ONC_1328	Verzenio (abemaciclib)	Negative change	Add inclusion criteria: B.Breast Cancer 1.The member has node positive, ER/PR positive, HER2 negative high risk early stage breast cancer (high risk is defined as any ONE of the following : ≥4 positive axillary lymp nodes OR 1-3 nodes and either tumor size ≥5 cm, histologic grade 3, or centrally tested Ki-67 ≥20%) AND Verzenio (abemaciclib) will be used in combination with tamoxifen or an aromatase inhibitor as adjuvant treatment for up to 2 years.	Per Clinical Trial Analysis/Criteria	
UM ONC_1344	Poteligeo (mogamulizumab-kpkc)	Negative change	Add inclusion criteria: B.Mycosis Fungoides/Sezary Syndrome 1.Poteligeo (mogamulizumab-kpkc) will be used as a single agent for relapsed or refractory stage IIB-IVB mycosis fungoides/Sezary syndrome and the member has received and experienced disease progression on Istodax (romidepsin). ~~AND~~ ~~1.The member has received and experienced disease progression on ALL of the following:~~ ~~a.Istodax (romedepsin)~~ ~~b.Targretin (bexaratene)~~	Per Clinical Trial Analysis/Criteria	
UM ONC_1384	Targretin (bexarotene)	Negative change	Add inclusion criteria: B.Cutaneous T-Cell Lymphoma (CTCL) 1.The member has relapsed/refractory stage IIB-IV cutaneous T-cell lymphoma (all variants) or mycosis fungoides/Sezary syndrome AND 2.The member is refractory or intolerant to at least 2 ~~1~~ prior therap~~ies~~y AND 3.Targretin (oral bexarotene) is being used as a single agent.	Per Clinical Trial Analysis/Criteria	
UM ONC_1384	Targretin (bexarotene)	Positive change	Remove exclusion criteria: B.Concurrent use with oral retinoid therapy.	Per Clinical Trial Analysis/Criteria	

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UM ONC_1391	Thalomid (thalidomide)	Positive change	Add inclusion criteria: B.Multiple Myeloma 1.The member has multiple myeloma and Thalomid (thalidomide) is being used as ONE of the following: a.Combination with dexamethasone +/- Velcade (bortezomib) +/- Darzalex/Darzalex Faspro (daratumumab) as initial line of therapy b.In VTD-PACE (bortezomib, dexamethasone, thalidomide, cisplatin, doxorubicin, cyclophosphamide, and etoposide) regimen as initial or subsequent line of therapy . c.In DT-PACE (dexamethasone, thalidomide, cisplatin, doxorubicin, cyclophosphamide, and etoposide) regimen as subsequent line of therapy.	Per Compendia Listing	
UM ONC_1391	Thalomid (thalidomide)	Negative change	Add exclusion criteria: A.Dosing exceeds single dose limit of Thalomid (thalidomide) 4200 mg.	Per Compendia Listing	
UM ONC_1419	Danyelza (naxitamab-gqgk)	Positive change	Add inclusion criteria: B.Neuroblastoma 1.Danyelza (naxitamab-gqgk) will be given in combination with GM-CSF for pediatric members one year of age and older, and adult members with relapsed or refractory high-risk neuroblastoma in bone or bone marrow demonstrating a partial response, minor response, or stable disease to prior therapy. High risk neuroblastoma is defined as members who are older than 18 months of age and have disseminated disease, or localized disease with unfavorable markers such as MYCN amplification (see Attachment A).	Per Clinical Trial Analysis/Criteria	
UM ONC_1419	Danyelza (naxitamab-gqgk)	Negative change	Add exclusion criteria: A.Disease progression while taking Danyelza (naxitamab-gqgk) or prior anti-disialoganglioside (GD2) antibody therapy [e.g., Unituxin (dinutuximab)].	Per Clinical Trial Analysis/Criteria	
UM ONC_1426	Pepaxto (melphalan flufenamide)	No Clinical Changes	Will archive Pepaxto policy. Manufacturer withdrew Pepaxto and is no longer on the market in the US.	Archive policy	