Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes	Post UMC comments
New	Fyarro (sirolimus)	n/a	n/a	n/a	
UM ONC_1028	Avastin (bevacizumab)/Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr)	Negative change	Add exclusion criteria: A.Avastin (bevacizumab)/Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr) is being used on or after disease progression on a bevacizumab containing regimen; except in colorectal cancer, bevacizumab may be used up to 2 lines of therapy after progression on a bevacizumab containing regimen in the metastatic setting.	Per Compendia Listing	
UM ONC_1038	Emend (Aprepitant oral or Fosaprepitant), Cinvanti (aprepitant injection) and Varubi (rolapitant oral/injection)	Positive change	Add inclusion criteria: b.Low or minimal emetogenic risk chemotherapy in members who have failed or are intolerant to or have a contraindication to Zofran (ondansetron), ~~OR~~ Kytril (granisetron), or Aloxi (palonosetron).	Step Therapy Criteria	
UM ONC_1039	Faslodex (fulvestrant)	Positive change	Remove inclusion criteria: B.Metastatic Breast Cancer ER/PR positive 1.NOTE: NCH Pathway L1 Preferred Regimens for ER/PR positive metastatic breast cancer, for first line/initial therapy are Kisqali (ribociclib)/Ibrance (Palbociclib) + Aromatase Inhibitor. Verzenio (abemaciclib)/Ibrance (Palbociclib) +/- Faslodex (fulvestrant) is preferred in the subsequent or second line setting.	Per Clinical Trial Analysis/Criteria	
UM ONC_1039	Faslodex (fulvestrant)	Negative change	Add inclusion criteria: B.Metastatic Breast Cancer ER/PR positive 1.The member has advanced or metastatic breast cancer and is post-menopausal or if the member is pre-menopausal and receiving concomitant ovarian ablation/suppression, Faslodex (fulvestrant) may be used as ANY of the following: a. In combination with an aromatase inhibitor (e.g., anastrozole, letrozole) b.In combination with Afinitor (everolimus) as second line or subsequent line of therapy c.In combination with a CDK4/6 inhibitor e.g. palbociclib, abemaciclib, ribociclib d.In combination with Piqray (alpelisib), if tumor is PIK3CA mutation positive, as second line therapy or subsequent line of therapy e.In combination with trastuzumab for HER2 positive disease. f.As a single agent.	Per Compendia Listing	
UM ONC_1042	Somatostatin Analog: Sandostatin (octreotide) and Somatuline	Negative change	Remove inclusion criteria: Remove Bynfezi, no longer available on the market	Other: Bynfezi no longer available on the market	
UM ONC_1132	Rituxan Products (Rituxan, Rituxan Hycela, Truxima, Ruxience)	Positive change	Add inclusion criteria: B.CD-20 positive B-Cell Non-Hodgkin's Lymphomas (NHL) or Acute Leukemia (B-AL) 1.The member is an adult or pediatric member ≥6 months of age who has CD20 positive B-cell NHL or B-AL and rituximab (Truxima or Ruxience) is being used as a single agent or in combination with chemotherapy	New FDA Indication	
UM ONC_1132	Rituxan Products (Rituxan, Rituxan Hycela, Truxima, Ruxience)	Negative change	Add exclusion criteria: B.Dosing exceeds single dose limit of rituximab products 500 mg/m² (CLL) and 375 mg/m2 (NHL); ~~and~~ Rituxan Hycela 1600 mg (CLL) and 1400 mg (NHL).	Per Compendia Listing	
UM ONC_1135	Vectibix (panitumumab)	Positive change	Add inclusion criteria: B.KRAS/NRAS- Wild Type Metastatic/Recurrent/ Unresectable Colorectal Cancer 1. ~~In combination with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or FOLFIRI (fluorouracil, leucovorin, and irinotecan) for members who have not received prior therapy containing either panitumumab or cetuximab/as therapy for~~ The member has KRAS/NRAS/BRAF wild-type gene and left-sided only ~~tumors~~ metastatic colorectal cancer and Vectibix (panitumumab) will be used in combination with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or FOLFIRI (fluorouracil, leucovorin, and irinotecan) OR 2.As a single agent or in combination with irinotecan for subsequent therapy following prior chemotherapy for metastatic disease	Per Compendia Listing	
UM ONC_1177	Gleevec (imatinib mesylate)	Negative change	Add inclusion criteria: B. Philadelphia Chromosome Positive Chronic myeloid leukemia (CML) 1.NOTE: In the absence of a resistant mutation (i.e., a mutation that confers resistance to imatinib), the preferred agent for initial therapy in Philadelphia chromosome positive CML is generic IMATINIB over other tyrosine kinase inhibitors (e.g., nilotinib, dasatinib,ponatinib, or bosutinib). This recommendation is based on a lack of Level 1 evidence (randomized trials and or meta-analyses) to show that one tyrosine kinase inhibitor is superior to another. 2.Imatinib use is supported as a single agent in adult and pediatric members for all phases of Philadelphia chromosome + CML, including before and after marrow transplant.	More Cost Effective Alternative(s)	

Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes	Post UMC comments
UM ONC_1177	Gleevec (imatinib mesylate)	Negative change	Add inclusion criteria: C.Philadelphia Chromosome Positive Acute lymphoblastic leukemia (ALL) 1.NOTE: Per NCH Policy & NCH Pathway the preferred tyrosine kinase inhibitor for this disease, is generic IMATINIB, unless the member is intolerant to/has disease that is refractory to imatinib. This recommendation is based on a lack of Level 1 evidence (randomized trials and or meta-analyses) to show that one tyrosine kinase inhibitor (e.g., nilotinib, dasatinib, ponatinib, or bosutinib).is superior to another. 2.Imatinib may be used in adult and pediatric members as a single agent or in combination with chemotherapy for initial or subsequent therapy of Philadelphia chromosome + ALL. E.Melanoma 1.The member has metastatic or unresectable melanoma with activating mutations of C-KIT and imatinib will be used as subsequent therapy following a BRAF targeted therapy (e.g., vemurafenib, dabrafenib, encorafenib). F.Myelodysplatic syndrome (MDS) 1.The member has MDS or myeloproliferative disease associated with PDGFR (platelet-derived growth factor receptor) gene rearrangements (i.e. Chronic myelomonocyte leukemia, atypical chronic myeloid leukemia, juvenile myelomonocyte leukemia) and imatinib will be used as monotherapy. G.Gastrointestinal stromal tumors (GIST) 1.NOTE: The preferred agent, per NCH Pathway & NCH Policy, for adjuvant therapy (for surgically resected disease) and for primary/initial therapy of unresectable/recurrent/metastatic disease is generic IMATINIB. This recommendation is based on a lack of Level 1 evidence (randomized trials and or meta-analyses) to show that another tyrosine kinase inhibitor (e.g., sunitinib, regorafenib, avapritinib, ripretinib) is superior to imatinib. 2.The member has a diagnosis of CD117 (Kit) positive GIST AND Imatinib is being used as monotherapy H.Dermatofribrosarcoma protuberans (DFSP) 1.The member has DFSP ~~positive for t(17;22) translocation~~ AND 2.Imatinib is being used as monotherapy ~~one of the following:~~ a. ~~As adjuvant therapy in members with positive surgical margins following excision~~	More Cost Effective Alternative(s); Per Compendia listing	
UM ONC_1203	Adcetris (brentiximab)	Negative change	Add inclusion criteria: B.Classical Hodgkin Lymphoma 1.NOTE: The preferred regimen for first line therapy in stage III and IV classical Hodgkin's Lymphoma, per NCH Policies and NCH Pathways, is ABVD (doxorubicin, bleomycin, vinblastine, dacarbazine) except in members with contraindications or intolerance to Bleomycin (e.g. lung disease, prior smoking history) AND IPS- International Prognostic Score of 2-7 (see below). This recommendation is based on the lack of Level 1 evidence (randomized trials and or meta-analyses) to show that Brentuximab + AVD has an overall survival advantage over ABVD.	Per Clinical Trial Analysis/Criteria	
UM ONC_1208	Zytiga or Yonsa (abiraterone acetate)	Negative change	Add inclusion criteria: B.Prostate Cancer 1.NOTE: For members who have not previously received Zytiga (abiraterone), Erleada (apalutamide), or Xtandi (enzalutamide), the preferred first line oral agent, per NCH Policies and NCH Pathway, for metastatic castrate sensitive prostate cancer (M1 disease) is Zytiga (abiraterone) acetate over Xtandi (enzalutamide). Generic abiraterone 250 mg tablet is preferred over abiraterone 500 mg tablet when available/possible for the indications listed below. This recommendation is based on the lack of Level 1 evidence (randomized trials and or meta-analyses) to show that Xtandi (enzalutamide) is superior to Zytiga (abiraterone). 2.Abiraterone is NOT indicated for Castrate-Resistant or Castrate Sensitive NON-METASTATIC prostate cancer (M0 disease with no radiographically visible metastases).	Per Clinical Trial Analysis/Criteria; Per compending listing	
UM ONC_1208	Zytiga or Yonsa (abiraterone acetate)	Negative change	Add exclusion criteria: A.Abiraterone is NOT indicated for Castrate-Resistant or Castrate Sensitive NON-METASTATIC prostate cancer (M0 disease with no radiographically visible metastases). metastases). E.Do not exceed Zytiga 120 (250 mg) or 60 (500 mg); or Yonsa ~~30~~ 120 (~~500~~ 125 mg) tablets/month.	Per FDA labeling	
UM ONC_1218	Provenge (sipuleucel-T)	Negative change	Add inclusion criteria: B.Prostate Cancer 2.NOTE: The preferred agents, per NCH Policies, for any line therapy of castration-resistant metastatic (M1) disease include Androgen Deprivation Therapy, with or without Zytiga (abiraterone), Xtandi (enzalutamide), OR Taxotere (docetaxel), over Provenge (sipuleucel-T). This recommendation is based on the lack of Level 1 evidence (randomized trials and or meta-analyses) to show that Provenge (sipuleucel-T) is superior when compared to the above agents.	Per Clinical Trial Analysis/Criteria	

Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes	Post UMC comments
UM ONC_1224	Kyprolis (carfilzomib)	Negative change	Add inclusion criteria: B.Multiple Myeloma (MM) 1.NOTE 1: Per NCH policy and pathway, the preferred Proteasome inhibitor is Velcade (bortezomib) over Kyprolis (carfilzomib) or Ninlaro (ixazomib) for first line therapy of newly diagnosed disease and first line therapy for myeloma in first relapse, unless there is a contraindication/intolerance/disease progression on Velcade (bortezomib)-based therapy. Please refer to UM ONC_1136 Velcade (bortezomib) policy. This recommendation is based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) to show superior outcomes with one proteosome inhibitor (e.g., bortezomib, carfilzomib, or ixazomib) over another.	Per Clinical Trial Analysis/Criteria	
UM ONC_1233	Tykerb (lapatinib)	Positive change	Remove inclusion criteria: 3.For relapsed or refractory disease, Kyprolis (carfilzomib) may be used ~~for members who have had prior progression on Velcade (bortezomib) based therapy~~ in ANY of the following: d. In combination with dexamethasone and pomalidomide if the member has failed 2 prior regimens or line of therapies that include one proteasome inhibitor (e.g., bortezomib, ixazomib, carfilzomib) & one immunomodulatory agent (e.g., lenalidomide, thalidomide).	Per NCH L1 Pathway; Per compendia listing	
UM ONC_1235	Doxil or Lipodox (liposomal doxorubicin)	Negative change	Add inclusion criteria: B.NOTE: The preferred agent, per NCH Policies, is standard Doxorubicin (Adriamycin) when used for Hodgkin lymphoma and breast cancer, Doxil/Lipodox (liposomal doxorubicin) is non-preferred in these settings. C.Aids related Kaposi's Sarcoma (KS) 1.For the treatment of HIV-related Kaposi's sarcoma as a single agent or in combination with antiretroviral therapy, as initial or subsequent line systemic therapy. ~~in members with disease that has progressed on prior combination chemotherapy or in members who are intolerant to other therapy.~~	More Cost Effective Alternative(s)	
UM ONC_1235	Doxil or Lipodox (liposomal doxorubicin)	Positive change	Remove inclusion criteria: C.Aids related Kaposi's Sarcoma (KS) 1.For the treatment of HIV-related Kaposi's sarcoma as a single agent or in combination with antiretroviral therapy, as initial or subsequent line systemic therapy. ~~in members with disease that has progressed on prior combination chemotherapy or in members who are intolerant to other therapy.~~	Per Compendia Listing	
UM ONC_1235	Doxil or Lipodox (liposomal doxorubicin)	Positive change	Add inclusion criteria: E.Multiple Myeloma 1.The member has relapsed or refractory multiple myeloma and Doxil/Lipodox (liposomal doxorubicin) will be used in combination with bortezomib (if have not previously received) +/- dexamethasone.	Per FDA labeling	
UM ONC_1258	Gilotrif (afatinib)	Negative change	Add inclusion criteria: on-Small Cell Lung Cancer (NSCLC) 1.NOTE: The preferred agent, per NCH Policy & NCH Pathway, for first line therapy of recurrent/metastatic, EGFR mutation positive Non-Small Cell Lung Cancer is Osimertinib. Please refer to UM ONC_1287 Tagrisso (osimertinib) policy. This recommendation is based on the lack of Level 1 evidence (randomized trials and or meta-analyses) to show Gilotrif (afatinib) is superior to Tagrisso (Osimertinib) for the first line treatment of EGFR mutation positive NSCLC.	Per Clinical Trial Analysis/Criteria	
UM ONC_1258	Gilotrif (afatinib)	Negative change	Add exclusion criteria: D.Treatment exceeds the maximum limit of 60 (20 mg), 30 (30 mg), or 30 (40 mg) tablets per month.	Per FDA labeling	
UM ONC_1259	Gazyva (obinutuzumab)	Negative change	Add inclusion criteria: B.Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)/ Follicular Lymphoma: 1.NOTE: The preferred agents for requests for Rituxan (rituximab) and Gazyva (obinutuzumab), per NCH Policy & NCH Pathway, are Truxima (rituximab-abbs) & Ruxience (rituximab-pvvr). Please refer to UM ONC_1132 Rituximab Products policy. This recommendation is based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) that shows superior outcomes with Gazyva (obinutuzumab) over rituximab products.	Per Clinical Trial Analysis/Criteria	
UM ONC_1259	Gazyva (obinutuzumab)	Negative change	Add exclusion criteria: A.Disease progression while taking Gazyva (obinutuzumab) or another anti-CD20 monoclonal antibody [e.g., Rituxan (rituximab)].	Per Clinical Trial Analysis/Criteria	
UM ONC_1260	Beleodaq (belinosat)	Negative change	Add inclusion criteria: Mycosis Fungoides/Sezary Syndrome (Stage IIB-IV)	Per Clinical Trial Analysis/Criteria	

Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes	Post UMC comments
UM ONC_1263	Keytruda (pembrolizumab)	Positive change	Add inclusion criteria: B.Melanoma 1.Keytruda (pembrolizumab) will be used as single agent for ONE of the following: a. In adult or pediatric members ≥12 years of age as adjuvant therapy for ~~high risk~~ Stages IIb, IIc, and III melanoma following complete resection of the primary tumor (when identified) with or without a complete regional lymph node dissection. NOTE: The maximum total duration of therapy is 1 year in the adjuvant setting. c.NOTE: Preferred weight-based dosing: Keytruda (pembrolizumab) 200 mg (if 50 kg or more) or 2 mg/kg (if less than 50 kg) for every 3 weeks dosing. The FDA approved pediatric dose is 2 mg/kg (up to a maximum of 200 mg) every three weeks.	New FDA Indication	
UM ONC_1280	Darzalex and Darzalex Faspro (daratumumab)	Positive change	Add inclusion criteria: 2.NOTE 2: Subcutaneous daratumumab, Darzalex Faspro, may be substituted for IV daratumumab, as part of the preferred NCH pathway regimens, and for all the indications listed in this policy. 3.NOTE 3: First line daratumumab based regimens are non-preferred per NCH Policy and NCH Pathway, for both transplant eligible and transplant ineligible multiple myeloma. This position is based on the lack of Level 1 evidence (randomized trial) showing the superiority of daratumumab- based first line regimens compared to standard RVd-Revlimid Velcade Dexamethasone and long term follow up of the RVd regimen showing excellent long term outcomes. Please refer to NCH Pathway for the preferred first line regimens recommended for use in multiple myeloma. 4.Daratumumab may be used in members with relapsed/refractory multiple myeloma as a part of the following preferred NCH pathway regimens: •Daratumumab + Carfilzomib + Steroid	New FDA Indication; Per NCH L1 Pathway	
UM ONC_1346 Prev. UM_1049	Copiktra (duvelisib)	Negative change	Remove inclusion criteria: B.Indolent Non Hodgkin's Lymphoma (Follicular Non-Hodgkin Lymphoma (NHL), Marginal Zone Lymphoma) 1.Copiktra (duvelisib) may be used as monotherapy for members with relapsed Indolent NHL who have experienced disease progression on or after 2 prior lines of therapy (prior therapies must have included any 2 of the following): rituximab monotherapy/rituximab + chemotherapy/RIT- Radio Immuno-Therapy (e.g., Zevalin).	FDA/NCCN Withdrawal	
UM ONC_1401	Tukysa (tucatinib)	Positive change	Remove inclusion criteria: B.Breast Carcinoma 1.NOTE: Tukysa (tucatinib) is a non-preferred agent per NCH Policy & NCH Pathway. Tykerb (lapatinib) is the preferred agent in clinical situations where Tukysa (tucatinib) is indicated. This position is based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) to show superior clinical outcomes with [Tukysa (tucatinib) + capecitabine + trastuzumab] compared to [Tykerb (lapatinib) + capecitabine + trastuzumab]. 2.Tukysa (tucatinib) may be used in members with recurrent unresectable or metastatic HER-2 positive breast cancer, if there is an intolerance/contraindication to lapatinib use AND the following criteria are met: a.Member has metastatic HER-2 positive breast cancer, with or without brain metastases AND b.The member has experienced disease progression on prior therapy with [Herceptin (trastuzumab) + Perjeta (pertuzumab) +/- Taxane] AND disease progression on Kadcyla (trastuzumab emtansine) in the metastatic AND c.Tukysa (tucatinib) will be used in combination with Herceptin (trastuzumab) and Xeloda (capecitabine).	Per Clinical Trial Analysis/Criteria	
UM ONC_1401	Tukysa (tucatinib)	Positive change	Add inclusion criteria: B.Breast Carcinoma 1.Tukysa (tucatinib) may be used in combination with trastuzumab (i.e., Kanjinti or Ogivri) and Xeloda (capecitabine) in members with recurrent unresectable or metastatic HER-2 positive breast cancer, with or without brain metastases, following prior anti-HER2 based regimen(s) in the metastatic setting.	Per FDA labeling	
UM ONC_1405	Retevmo (selpercatinib)	Positive change	Remove inclusion criteria: B.Non-Small Cell Lung Cancer 1.NOTE: Per NCH L1 pathway and NCH policy, Retevmo (selpercatinib) is preferred over Gavreto (pralsetinib) for RET fusion positive advanced, recurrent, or metastatic NSCLC. C.Thyroid Cancer 1.NOTE: Per NCH L1 pathway and NCH policies, Retevmo (selpercatinib) is preferred over Gavreto (pralsetinib) for RET-mutation /RET-fusion positive medullary and non-medullary thyroid cancer (e.g., papillary, follicular, or Hurthle cell thyroid cancer).	Per Clinical Trial Analysis/Criteria	

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UM ONC_1405	Retevmo (selpercatinib)	Positive change	Add inclusion criteria: C.Thyroid Cancer 2.Adult and pediatric members ≥ 12 years of age with RET- fusion/RET-mutation positive thyroid cancer (all non-Medullary histology's are included- Anaplastic/Follicular/Hurthle Cell/Papillary Carcinoma) who require systemic therapy and have disease that is refractory to radioactive iodine (if radioactive iodine is appropriate therapy for their thyroid cancer and- their cancer is positive for radioactive iodine uptake on appropriate scanning)	Per Compendia Listing	
UM ONC_1405	Retevmo (selpercatinib)	Negative change	Add exclusion criteria: D.Dosing exceeds single dose limit of Retevmo (selpercatinib) ~~320~~ 160 mg.	Per FDA labeling	
UM ONC_1414	Gavreto (pralsetinib)	Positive change	Remove inclusion criteria: B.Non-Small Cell Lung Cancer (NSCLC) 1.NOTE: Per NCH L1 pathway and NCH policies, Retevmo (selpercatinib) is preferred over Gavreto (pralsetinib) for RET fusion positive advanced, recurrent, or metastatic NSCLC due to lack of Level 1 evidence supporting superiority of Gavreto (pralsetinib) over Retevmo (selpercatinib). Please refer to NCH Policy UM ONC_1405 Retevmo (selpercatinib). C.Thyroid Cancer 1.NOTE: Per NCH L1 pathawy and NCH policies, Retevmo (selpercatinib) is preferred over Gavreto (pralsetinib) for RET-mutation/RET-fusion positive medullary and non-medullary thyroid cancer. Please refer to NCH Policy UM ONC_1405 Retevmo (selpercatinib).	Per Clinical Trial Analysis/Criteria	
UM ONC_1414	Gavreto (pralsetinib)	Positive change	Add inclusion criteria: C. Thyroid Cancer 2.Adult and pediatric members ≥ 12 years of age with RET- fusion/RET-mutation positive Non-Medullary thyroid cancer (e.g., papillary, follicular, or Hurthle cell, or anaplastic thyroid cancer) who require systemic therapy and have disease that is refractory to radioactive iodine (if radioactive iodine is appropriate therapy for their thyroid cancer and- their cancer is positive for radioactive iodine uptake on appropriate scanning)	Per Compendia Listing	