Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
New	Elahere (mirvetuximab soravtansine-gynx)	N/A	N/A	N/A
UM ONC_1039	Faslodex (fulvestrant)	Positive change	Add inclusion criteria: B. ~~Metastatic~~ Breast Cancer ~~ER/PR positive~~ 1.The member has advanced or metastatic hormone receptor (ER/PR) positive 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 FDA labeling
UM ONC_1042	Somatostatin Analog	Positive change	Remove inclusion criteria: ~~7.NOTE: The preferred Somastatin Analog is Sandostatin IV/SC or LAR Depot (octreotide) over Somatuline Depot (lanreotide). Somatuline Depot (lanreotide) may be used in members with contraindication/intolerance to OR failure of Sandostatin IV/SC or LAR Depot (octreotide).~~	Per NCH Pathway expansion
UM ONC_1042	Somatostatin Analog	Positive change	Add inclusion criteria: B.NETS: Neuro Endocrine Tumors 1. ~~Sandostatin IV/SQ or LAR Depot (octreotide)~~ Sandostatin (octreotide LAR Depot/IV/SQ) or Somatuline Depot (lanreotide) is being used in members with metastatic/unresectable neuroendocrine tumors originating in the gastrointestinal tract/pancreas/lung/adrenal glands/other organs (except small cell lung cancer) as a single agent or in combination with other therapies. a.As symptom control in members with carcinoid syndrome or symptoms suggestive of carcinoid syndrome, e.g., diarrhea, flushing AND/OR b.For tumor/disease control. C.Thymomas and Thymic Carcinomas 1.The member has unresectable/metastatic thymoma or thymic carcinomas AND 2.The tumor/disease is positive on an Octreoscan (or similar imaging confirming that the tumor is somatostatin receptor positive) AND 3. ~~Sandostatin IV/SQ or LAR Depot (octreotide)~~ Sandostatin (octreotide LAR Depot/IV/SQ) or Somatuline Depot (lanreotide) is being used for locally advanced/metastatic disease with or without prednisone. D.Meningiomas 1. ~~Sandostatin IV/SQ or LAR Depot (octreotide)~~ Sandostatin (octreotide LAR Depot/IV/SQ) or Somatuline Depot (lanreotide) is being used for recurrent or progressive disease, when radiation is not possible, and the octreotide scan is positive.	Per NCH Pathway expansion
UM ONC_1043	Tarceva (Erlotinib)	Negative change	Remove inclusion criteria: B.Non-Small Cell Lung Cancer (NSCLC) 1.Tarceva (erlotinib) may be used as a single agent for recurrent/metastatic, EGFR mutation positive NSCLC if the member has an intolerance/contraindication to Tagrisso (osimertinib). 2.NOTE: Per NCH Pathway & NCH Policy, [Tarceva (erlotinib) + Cyramza (ramucirumab)] and [Tarceva (erlotinib) + Avastin (bevacizumab)/bevacizumab biosimilar products] are non-Preferred regimens for the treatment of NSCLC. ~~The preferred agent for first line therapy of recurrent/metastatic, EGFR mutation positive (exon 19 deletion or L858R) Non-Small Cell Lung Cancer is Tagrisso (osimertinib) based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) to support that single agent Tarceva (erlotinib) or Tarceva (erlotinib) containing regimen is superior to Tagrisso (osimertinib).1 Please see UM ONC_1287 Tagrisso™ (osimertinib) policy.~~ 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 recommended alternatives agents/regimens, including but not limited to regimens at http://pathways.newcenturyhealth.com. C. Pancreatic Cancer ~~1.Tarceva (erlotinib) may be used in combination with Gemzar (gemcitabine) in members with advanced, unresectable, or metastatic pancreatic cancer as initial or subsequent therapy.~~ 1.NOTE: Per NCH Policy, Tarceva (erlotinib) + Gemzar (gemcitabine) is a non-preferred regimen for the treatment of advanced, unresectable, or metastatic pancreatic cancer as initial or subsequent therapy. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with compared to NCH alternative agents/regimens, including but not limited to regimens at http://pathways.newcenturyhealth.com.	Per NCH Pathway exclusion
UM ONC_1072	Myeloid Growth Factors	Positive change	Add inclusion criteria: Add Intermediate FN risk table and updates to low and high FN risk tables	Per Compendia Listing
UM ONC_1135	Vectibix (panitumumab)	Positive change	Add inclusion criteria: B. ~~KRAS/NRAS- Wild Type- Metastatic/Recurrent/ Unresectable~~ Colorectal Cancer 1.The member has KRAS/NRAS/BRAF wild-type gene and left-sided only metastatic colorectal cancer and Vectibix (panitumumab) will be used in ANY of the following clinical settings: a. Iin combination with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or FOLFIRI (fluorouracil, leucovorin, and irinotecan) OR b.As a single agent or in combination with irinotecan for subsequent therapy following prior chemotherapy for metastatic disease ~~. OR~~ 2.Vectibix (panitumumab) may be used as subsequent therapy in combination with Braftovi (encorafenib) for patients with unresectable/ metastatic disease (BRAF V600E mutation positive), regardless of KRAS/NRAS status.	Per Compendia Listing
UM ONC_1135	Vectibix (panitumumab)	Negative change	Add exclusion criteria: B.Absence of documented KRAS/NRAS/BRAF testing and results of such testing for the above indications.	Per FDA labeling
UM ONC_1177	Gleevec (imatinib mesylate)	N/A	N/A	Archive policy- add to generic drug policy

UM ONC_1179	Abraxane (nab-paclitaxel)	Negative change	Add inclusion criteria: B.Breast Cancer 1.NOTE: Per NCH Policy, Abraxane (nab-paclitaxel) +/- Keytruda (pembrolizumab) is a non-preferred drug for the treatment of recurrent unresectable or metastatic breast cancer. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes compared to Taxol (paclitaxel) or Taxotere (docetaxel). The use of solvent-based Taxol (paclitaxel) or Taxotere (docetaxel) is preferred over Abraxane (nab-paclitaxel) unless there is a history of a severe allergic reaction/anaphylaxis to solvent-based Taxol (paclitaxel) or Taxotere (docetaxel).	Per NCH Pathway exclusion
UM ONC_1195	Votrient (pazopanib)	Positive and Negative change	Add inclusion criteria: B. ~~Advanced/Metastatic~~ Renal Cell Carcinoma ~~1.NOTE: The preferred tyrosine kinase inhibitor, per NCH Policy & NCH Pathway for first line advanced/metastatic renal cell carcinoma, for IMDC Good Risk (Favorable Risk) Disease is Votrient (pazopanib).~~ ~~3.Votrient (pazopanib) use is supported as a single agent, for first line therapy of recurrent/metastatic renal cell carcinoma AND IMDC Criteria Favorable Risk Disease.~~ ~~4.Votrient (pazopanib) use is supported as a single agent, for subsequent line therapy for recurrent/metastatic renal cell carcinoma regardless of IMDC Risk Category.~~ 1.Votrient (pazopanib) may be used in members with recurrent/metastatic renal cell carcinoma for ANY of the following clinical settings: a.As a single agent for first line therapy and IMDC Criteria Favorable Risk Disease OR b.As a single agent for subsequent line therapy, regardless of IMDC Risk category.	Per Clinical Trial Analysis/Criteria
UM ONC_1206	Xalkori (crizotinib)	Positive change	Remove inclusion criteria: B.Non-Small Cell Lung Cancer (NSCLC) ~~1.The member has locally advanced, recurrent, or metastatic NSCLC and Xalkori (crizotinib) may be used as a single agent for any of the following:~~ ~~a.ROS1 rearrangement-positive tumors as first line or subsequent therapy OR~~ ~~b.ALK-positive tumors for members who are intolerant to/have a contraindication to/have failed therapy with Alecensa (alectinib) or Alunbrig (brigatinib).~~ 1.The member has locally advanced, recurrent, or metastatic NSCLC and Xalkori (crizotinib) may be used as a single agent for ROS1 or ALK rearrangement positive tumors (confirmed by testing prior to initiation of treatment) as first line or subsequent therapy. 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~~ that is ALK fusion positive, confirmed prior to treatment. D.ALK+ Anaplastic Lymphoma (ALCL) 1.Xalkori (crizotinib) may be used as a single agent for members 21 years old or younger with relapsed/refractory Anaplastic Large Cell Lymphoma that is: a.Positive for ALK: Anaplastic Lymphoma Kinase (confirmed by testing prior to initiation of treatment) AND b.The member has experienced disease progression on at least one prior therapy.	Per NCH Pathway expansion
UM ONC_1206	Xalkori (crizotinib)	Negative change	Add exclusion criteria: B.Absence of documented ROS1/ALK testing and results of such testing for the above indications.	Per FDA labeling
UM ONC_1233	Tykerb (lapatinib)	N/A	N/A	Archive policy- add to generic drug policy
UM ONC_1260	Beleodaq (belinosat)	Negative change	Remove inclusion criteria: ~~CD30+ T-cell lymphoproliferative disorders, including cutaneous ALCL: As a single agent for relapsed/refractory disease~~ ~~Mycosis Fungoides/Sezary Syndrome (Stage IIB-IV): As a single agent for relapsed/refractory disease, with or without skin-directed therapy, e.g. ECP: Extra Corporeal Photopheresis~~ ~~As a single agent for first line therapy with or without radiation for local control~~	NCCN Withdrawal
UM ONC_1263	Keytruda (pembrolizumab)	Negative change	Remove inclusion criteria: Q.Triple Negative Breast Cancer (TNBC) 1.Keytruda (pembrolizumab) may be used for the following: a.As a part of neoadjuvant therapy in combination with chemotherapy and subsequent adjuvant therapy in a member with newly diagnosed high-risk early-stage TNBC (a tumor size greater than 1 cm, less than or equal to 2 cm in diameter with nodal involvement, or tumor size greater than 2 cm in diameter regardless of nodal involvement. NOTE Keytruda may be used as a part of the member'sadjuvant therapy ONLY if the member received pembrolizumab in the neoadjuvant setting. ~~b.In members with locally recurrent unresectable or metastatic TNBC whose tumors express PD-L1 with a Combined Positive Score (CPS) greater than or equal to 10.~~ b.NOTE: Per NCH Policy, Keytruda (pembrolizumab) + Abraxane (nab-paclitaxel) is non-preferred for members with locally recurrent unresectable or metastatic TNBC whose tumors express PD-L1 with a Combined Positive Score (CPS) greater than or equal to 10. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) show superior outcomes compared to Taxol (paclitaxel) or Taxotere (docetaxel). The use of solvent-based Taxol (paclitaxel) or Taxotere (docetaxel) is preferred over Abraxane (nab-paclitaxel) unless there is a history of a severe allergic reaction/anaphylaxis to solvent-based Taxol (paclitaxel) or Taxotere (docetaxel).	Per NCH Pathway exclusion
UM ONC_1282	Imlygic (Talimogene Laherparepvec)	Negative change	Add inclusion criteria: B.Melanoma 1.Imlygic (talimogene laherparepvec) may be used as a single agent (as an intra-lesional injection) for unresectable cutaneous, subcutaneous, and nodal lesions, in members with melanoma recurrence after prior surgery OR 2.Imlygic (talimogene laherparepvec) may be used as a single agent as neo-adjuvant (preoperative) therapy for resectable stage IIIB-IVM1a melanoma. 3.NOTE: Imlygic (talimogene laherparepvec) in combination with Yervoy (ipilimumab) ~~an Immune Checkpoint Inhibitor (e.g., ipilimumab, nivolumab, pembrolizumab)~~ is non-Preferred per NCH Policy. 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 recommended alternative agents/regimens, including but not limited to regimens at recommended by NCH (http://pathways.newcenturyhealth.com).	Per NCH Pathway exclusion

UM ONC_1290	Yondelis (trabectedin)	Negative change	Add inclusion criteria: B.Soft Tissue Sarcoma 1.The member has unresectable or metastatic soft tissue sarcoma (Leiomyosarcoma, liposarcoma, and translocation-related sarcomas) AND Yondelis (trabectedin) will be used as monotherapy following disease progression with an anthracycline-based chemotherapy, unless there is a contraindication/intolerance with prior anthracycline based therapy. 2.NOTE: Per NCH Policy, the use of Yondelis (trabectedin) is non-preferred for the treatment for other soft tissue sarcoma histologies that are not leiomyosarcoma, liposarcoma, and translocation-related sarcomas. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with compared to alternative agents/regimens recommended by NCH (http://pathways.newcenturyhealth.com).	Per NCH Pathway exclusion
UM ONC_1304	Generic Drugs	Positive change	Add inclusion criteria: Add Tykerb and Gleevec to table of generic drugs	More Cost Effective Alternative(s)
UM ONC_1307	Zejula (niraparib)	Negative change	Add inclusion criteria: B.Ovarian Cancer 1.Zejula (niraparib) ~~monotherapy~~ may be used as monotherapy as follows: a.The member has newly diagnosed stage II-IV ovarian carcinoma and has undergone surgery (with or without optimal debulking) and has completed first line platinum-based chemotherapy AND Zejula (niraparib) is being used as a single agent ~~for~~ maintenance therapy ~~(regardless of BRCA mutation test results)~~ for members who are BRCA 1 or 2 mutation positive as confirmed by an FDA approved test OR b.The member has recurrent platinum-sensitive ovarian cancer and Zejula (niraparib) is being used as a single agent for maintenance therapy, after completion of platinum-based chemotherapy and the member is BRCA 1 or 2 mutation positive as confirmed by an FDA approved test). 2.NOTE: Per NCH Policy, the use of Zejula (niraparib) as monotherapy is non-preferred for persistent disease or recurrence in members with/without deleterious germline BRCA 1 or 2 mutation who have been treated with two or more lines of chemotherapy. This recommendation is based on the FDA withdrawal, totality of evidence, and ASCO guideline updates (see references below) showing a lack of OS benefit with PARP inhibitor therapy versus standard chemotherapy in the treatment of relapsed, BRCA-mutated, high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer.	Per Compendia Listing
UM ONC_1307	Zejula (niraparib)	Negative change	Add exclusion criteria: B.Use of Zejula (niraparib) not to exceed more than 1 line of maintenance therapy for recurrent ovarian cancer. C.Lack of documentation for the detection of BRCA 1 or 2 mutation by an FDA approved test; a list of an FDA approved test is available at www.fda.gov/CcompanionDiagnostics.	Per Clinical Trial Analysis/Criteria
UM ONC_1359	Arranon (nelarabine)	Positive change	Remove inclusion criteria: B.T-Cell Acute Lymphoblastic Leukemia (T-ALL)/T-Cell Lymphoblastic Lymphoma (T-LBL) 1.The member has T-ALL/T-LBL and Arranon (nelarabine) may be used in adult and pediatric members 1 year and older for ANY of the following: a.Induction/Consolidation therapy as a component of a nelarabine containing regimen. b.Therapy for Relapsed/Refractory disease in members who have progressed after therapy with 2 or more regimens. ~~c.NOTE: Per NCH Pathway & NCH Policy, Arranon (nelarabine) + Venclexta (venetoclax) is a non-Preferred regimen for the treatment of T-ALL. 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. Please refer to NCH Pathway for the preferred treatments recommended for use in T-ALL.~~	More Cost Effective Alternative(s)
UM ONC_1361	Erwinaze (asparaginase Erwinia chrysanthemi)	Negative change	Add inclusion criteria: B.Acute Lymphoblastic Leukemia (ALL) 1.NOTE: Per NCH Policy ~~& NCH Pathway~~, ~~Oncaspar (pegasparagase) and Asparlas (calaspargase pegol-mknl) are preferred over~~ Erwinaze (erwinia asparaginase) and Rylaze (erwinia asparaginase recombinant) are non-preferred for all subtypes of ALL as a part of anti-leukemia therapy. This recommendation is based on the lack of Level 1 evidence (randomized clinical trials and/or meta-analyses) to show superior outcomes with Erwinia products over Oncaspar (pegasparagase) and Asparlas (calaspargase pegol-mknl). ~~- Please refer to UM ONC_1063 Oncaspar (pegaspargase) policy or UM ONC_1352 Asparlas (calaspargase pegol-mknl) policy.~~ 2.7.Erwinaze and Rylaze (asparaginase Erwinia chrysanthemi and recombinant-rywn) may be used in members with Philadelphia chromosome-negative ALL/Philadelphia chromosome positive ALL as a part of a multi-agent chemotherapy regimen and as therapy for induction/consolidation/relapsed/refractory disease, ~~unless~~ if the member has a history of hypersensitivity reaction or other adverse effects from Oncaspar (pegasparagase) or Asparlas (calaspargase pegol-mknl).	Per NCH Pathway exclusion
UM ONC_1361	Erwinaze (asparaginase Erwinia chrysanthemi)	Negative change	Add exclusion criteria: A. ~~Erwinaze and Rylaze (asparaginase Erwinia chrysanthemi and recombinant- rywn) is being used after d~~Disease progression with either Erwinaze (asparaginase erwinia chrysanthemi) or Rylaze (asparaginase erwinia recombinant- rywn). B.Dosing exceeds single dose limit of Oncaspar (pegasparagase) and Asparlas (calaspargase pegol-mknl) 2500 units/m2 (up to a maximum of 3,750 units/dose). B.C.Dosing exceeds single dose limit of Erwinaze (asparaginase Erwinia chrysanthemi) 25,000/m2 International Units or Rylaze (asparaginase Erwinia chrysanthemi recombinant- rywn) 25 mg/m2 (for every 48 hrs schedule) and 50 mg/m2 (for once per week schedule).	Per Compendia Listing
UM ONC_1365	Xpovio (selinexor)	Negative change	Add inclusion criteria: B.Multiple Myeloma 1.Xpovio (selinexor) may be used in combination with Dexamethasone (unless there is a contraindication or intolerance to Dexamethasone or another corticosteroid) for a member with relapsed/refractory multiple myeloma who has documented disease progression on at least 4 prior lines of therapy including two proteasome inhibitors (e.g., bortezomib, carfilzomib, ixazomib), two immunomodulatory agents (e.g., lenalidomide, thalidomide, pomalidomide), and an anti-CD38 monoclonal antibody [e.g., Darzalex (daratumumab) or Sarclisa (isatuximab-irfc)] OR 2.Xpovio (selinexor) may be used for relapsed/refractory multiple myeloma in combination with Bortezomib +/- Dexamethasone in members who have received one prior therapy. 3.NOTE: Per NCH Pathway & NCH Policy, Selinexor + Daratumumab +/- Dexamethasone is a non-Preferred regimen for the treatment of relapsed/refractory MM. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) ~~demonstrating superiority compared to NCH Preferred regimens. Please refer to NCH Pathway for the preferred treatments recommended for use in relapsed/refractory MM.~~to show superior outcomes with Xpovio (selinexor) compared to NCH recommended alternatives agents/regimens, including but not limited to regimens at http://pathways.newcenturyhealth.com.	Per NCH Pathway exclusion

UM ONC_1365	Xpovio (selinexor)	Negative change	Add exclusion criteria: C.Treatment exceeds the maximum limit of ~~20~~ 32 (20 mg), 16 (40 mg), 8 (50 mg), 8 (60mg) tablets/month.	Per FDA labeling
UM ONC_1414	Gavreto (pralsetinib)	Positive change	Remove inclusion criteria: A.Disease progression while taking Gavreto (pralsetinib) or another RET inhibitor (e.g., selpercatinib) ~~/MET inhibitor (e.g., vandetinib/cabozantinib).~~	Per Clinical Trial Analysis/Criteria
UM ONC_1457	Fyarro (intravenous sirolimus)	Negative change	Add inclusion criteria: B.Perivascular Epithelioid Cell Tumor (PEComa, Angiomyolipoma or Lymphangioleiomyomatosis) 1.NOTE: Per NCH policy, Fyarro (intravenous sirolimus) is non-preferred for the treatment of advanced unresectable or metastatic perivascular epithelioid cell tumor (PEComa, Angiomyolipoma, or Lymphangioleiomyomatosis). ~~the preferred MTOR inhibitor for the treatment of Perivascular Epithelioid Cell Tumor is Rapamune (oral sirolimus) over Fyarro (intravenous sirolimus).~~ This recommendation is based on the lack of of Level 1 evidence (randomized trials and/or meta-analyses) ~~that shows~~ to show superior outcomes with Fyarro (intravenous sirolimus) over Rapamune (oral sirolimus). 2.The member has locally advanced unresectable or metastatic perivascular epithelioid cell tumor (PEComa, Angiomyolipoma, or Lymphangioleiomyomatosis) and Fyarro (inravenous sirolimus) will be used as monotherapy AND the member is unable to tolerate or has a contraindication to the ~~preferred~~ oral formulation of sirolimus, Rapamune.	More Cost Effective Alternative(s)
UM ONC_1459	Kimmtrak (tebentafusp-tebn)	Positive change	Remove inclusion criteria: B.Uveal Melanoma 1.The member has HLA-A*02:01-positive unresectable or metastatic Uveal Melanoma and Kimmtrak (tebentafusp-tebn) may be used as monotherapy, if the member has tried and failed or has a contraindication/intolerance to NCH Preferred first line therapy which is the combination of [Opdivo (nivolumab) + Yervoy (ipilimumab)]. ~~2.NOTE: Per NCH Policy, Kimmtrak (tebentafusp-tebn) is Non-Preferred for the treatment of unresectable or metastatic Uveal Melanoma. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with Kimmtrak (tebentafusp-tebn) compared to [Opdivo (nivolumab) + Yervoy (ipilimumab)].~~	Per NCH Pathway expansion