

Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
New	Imjudo (tremelimumab)	N/A	N/A	N/A
New	Tecvayli (teclistamab-cqyv)	N/A	N/A	N/A
UM ONC_1028	Bevacizumab Products	Positive change	Remove inclusion criteria: F.Cervical Cancer 1.For members with metastatic/recurrent/unresectable cervical cancer and a tumor PD-L1 staining showing a CPS of ≥ 1%, the NCH preferred regimen, for initial/first line therapy, is cisplatin/carboplatin + paclitaxel + pembrolizumab WITHOUT bevacizumab. This recommendation is based on the trial (referenced below) by Colombo et al, which showed no added clinical benefit with the addition of bevacizumab to the above regimen.	Per NCH Pathway expansion
UM ONC_1028	Bevacizumab Products	Positive change	Add inclusion criteria: I.Brain Necrosis 1.Bevacizumab/bevacizumab biosimilar may be used for members with brain necrosis or edema due to cranial irradiation and has failed to achieve symptomatic response to steroids (e.g., dexamethasone, methylprednisolone, prednisone). Use of bevacizumab is not recommended in members with intracranial hemorrhage.	Per Compendia Listing
UM ONC_1028	Bevacizumab Products	Negative change	Add exclusion criteria: D.For Brain Necrosis: Treatment exceeds the maximum duration limit of 4 doses (dose range from 5 mg/kg every 2 weeks to 7.5 mg/kg every 3 weeks).	Per FDA labeling
UM ONC_1041	LHRH agonists and antagonist	Positive change	Add inclusion criteria: Add firmagon as preferred	More Cost Effective Alternative(s)
UM ONC_1041	LHRH agonists and antagonist	Negative change	Remove inclusion criteria: Remove Vantas, this is no longer on the market	No longer on the market
UM ONC_1072	Myeloid Growth Factors	Positive change	Add inclusion criteria: Add all short acting MGF as preferred over long acting MGF	More Cost Effective Alternative(s)
UM ONC_1072	Myeloid Growth Factors	Positive change	Add inclusion criteria: Add intermediate risk table and updates to low and high risk tables	Per NCH Pathway expansion
UM ONC_1072	Myeloid Growth Factors	Positive change	Add exclusion criteria: I.Dosing exceeds single dose limit for a short acting MGF (filgrastim product) 5 mcg/kg/day (rounded down to the nearest vial size in doses of 300 mcg for ≤ 60 kg or 480 mcg for > 60 kg) , <b>except when MGF is being used as a part of stem cell collection.</b>	Per FDA labeling
UM ONC_1089	Libtayo (cemiplimab-rwlc)	Positive change	Remove inclusion criteria: C.Basal Cell Carcinoma 1.Libtayo (cemiplimab-rwlc) may be used as a single agent, in members with locally advanced/recurrent/metastatic basal cell carcinoma, who are not candidates for surgery and/or radiation therapy. <b>and have failed prior therapy with or are intolerant to therapy with a Hedge Hog Pathway inhibitor (HHI). The preferred HHI per NCH Policy is Erivedge (vismodegib). Please see UM ONC_1222 Erivedge (vismodegib) policy.</b>	Per NCH Pathway expansion
UM ONC_1089	Libtayo (cemiplimab-rwlc)	Positive change	Add inclusion criteria: D.Non-Small Cell Lung Cancer (NSCLC) 1.The member has locally advanced, recurrent, or metastatic NSCLC, negative for the following actionable molecular markers ALK, EGFR, and ROS-1, and has not experienced disease progression on prior Immune Checkpoint Inhibitor therapy, including Keytruda (pembrolizumab), Opdivo (nivolumab), OR Tecentriq (atezolizumab) AND the following criteria are met: b.Libtayo (cemiplimab-rwlc) will be used as first line therapy in combination with platinum-based chemotherapy regardless of PD-L1 status.	New FDA Indication
UM ONC_1196	Sprycel (dasatinib)	No Clinical Changes	Section IIIA3 update: For Health Plans that utilize NCH UM Oncology Clinical Policies, and there is no Health Plan PDL applicable, the Preferred Drug Guidelines shall follow NCH recommended agents/regimens/preferred drugs	Other: NCH prefer drug guidelines
UM ONC_1203	Adcetris (brentuximab vedotin)	Positive change	Add inclusion criteria: C.Classical Hodgkin Lymphoma 2.Adcetris (brentuximab vedotin) may be used in combination with AVEPC (doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide) for members 2 years of age and older with previously untreated high risk classical Hodgkin lymphoma. High risk was defined as Ann Arbor Stage IIB with bulk disease, Stage IIIB, Stage IVA, and Stage IVB.	New FDA Indication
UM ONC_1203	Adcetris (brentuximab vedotin)	Negative change	Add exclusion criteria: C.Treatment with Adcetris (brentuximab vedotin) exceeds the maximum duration limit of <b>5 doses (as part of AVEPC for use in pediatrics);</b> 6 months cycles as a part of AAVD (12 doses for first line treatment of Hodgkin's Disease) OR exceeds 16 cycles for refractory/relapsed disease/consolidation treatment after HSCT OR exceeds 8 doses for previously untreated CD-30 + T Cell Lymphoma.	Per FDA labeling
UM ONC_1218	Provenge (sipuleucel-T)	No Clinical Changes	Section IIIA3 update: For Health Plans that utilize NCH UM Oncology Clinical Policies, and there is no Health Plan PDL applicable, the Preferred Drug Guidelines shall follow NCH recommended agents/regimens/preferred drugs	Other: NCH prefer drug guidelines
UM ONC_1263	Keytruda (pembrolizumab)	Positive change	Add inclusion criteria: H.Gastric Cancer or Esophageal and Esophagogastric Junction Cancers c.As second line or subsequent therapy as a single for esophageal squamous cell carcinoma with PD-L1 expression by CPS of 10 or higher	Per Compendia Listing
UM ONC_1263	Keytruda (pembrolizumab)	Positive change	Add inclusion criteria: I.Cervical Cancer 1.Keytruda (pembrolizumab) + Carboplatin/Cisplatin + Taxol (paclitaxel) may be used as first line <b>or subsequent therapy</b> for members with advanced/recurrent/metastatic cervical carcinoma whose tumors express PD-L1 CPS ≥ 1% OR 2.Keytruda (pembrolizumab) will be used in members with advanced /recurrent/metastatic cervical carcinoma whose tumors express PD-L1 CPS ≥ 1% as a single agent as second line or subsequent therapy following disease progression on or after prior chemotherapy treatment, with no exposure to prior Keytruda (pembrolizumab) or another Immune Checkpoint Inhibitor.	Per FDA labeling
UM ONC_1263	Keytruda (pembrolizumab)	Positive change	Add inclusion criteria: O.Cutaneous Squamous Cell Carcinoma (CSCC) 1.Keytruda (pembrolizumab) may be used as monotherapy for the treatment of members with recurrent, advanced, or metastatic cutaneous squamous cell carcinoma and is not a candidate for curative surgery and/or curative radiation.	Per FDA labeling
UM ONC_1263	Keytruda (pembrolizumab)	Positive change	Remove inclusion criteria: O.Cutaneous Squamous Cell Carcinoma (CSCC) 2.NOTE: Per NCH Policy, Keytruda (pembrolizumab) is a non-preferred checkpoint inhibitor for the treatment of members with recurrent or metastatic cutaneous squamous cell carcinoma. The preferred agent in the above setting is Libtayo (cemiplimab-rwlc). This position is based on the lack of Level 1 Evidence (randomized trials and/or meta-analyses) to show superior outcomes with Keytruda compared to Libtayo. Please refer to UM ONC_1089 for Libtayo (cemiplimab-rwlc) policy.	Per NCH Pathway expansion
UM ONC_1279	Cotellic (cobimetinib)	No Clinical Changes	Section IIIA3 update: For Health Plans that utilize NCH UM Oncology Clinical Policies, and there is no Health Plan PDL applicable, the Preferred Drug Guidelines shall follow NCH recommended agents/regimens/preferred drugs	Other: NCH prefer drug guidelines
UM ONC_1280	Darzalex and Darzalex Faspro (daratumumab)	No Clinical Changes	Section IIIA3 update: For Health Plans that utilize NCH UM Oncology Clinical Policies, and there is no Health Plan PDL applicable, the Preferred Drug Guidelines shall follow NCH recommended agents/regimens/preferred drugs	Other: NCH prefer drug guidelines
UM ONC_1284	Ninlaro (ixazomib)	Negative change	Remove inclusion criteria: B.Multiple Myeloma 1.Ninlaro (ixazomib) may be used for members who have experienced disease progression on, contraindications, or intolerance to NCH Preferred Velcade (bortezomib) based regimens in ANY of the following : a.As first line or subsequent therapy: <del>ixazomib +/- Dexamethasone +/- Lenalidomide</del> —ixazomib + Cyclophosphamide +/- Dexamethasone	NCCN Withdrawal
UM ONC_1284	Ninlaro (ixazomib)	Negative change	Add inclusion criteria: B.Multiple Myeloma 3.NOTE: Ixazomib/lenalidomide/dexamethasone is a non-preferred regimen for initial/primary treatment of multiple myeloma. 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 <a href="http://pathways.newcenturyhealth.com">http://pathways.newcenturyhealth.com</a> .	Per NCH Pathway exclusion

			Add inclusion criteria: C.Hepatocellular Carcinoma 1.The member has unresectable hepatocellular carcinoma with no prior systemic treatment, including prior checkpoint inhibitor (e.g., dostarlimab-gxly, atezolizumab, nivolumab, pembrolizumab, ipilimumab) AND 2.Imfinzi (durvalumab) will be used as first line therapy in combination with Imjudo (tremelimumab) [Imjudo is given for one cycle] followed by single agent Imfinzi (durvalumab). D.Non-Small Cell Lung Cancer (NSCLC) 2.Imfinzi (durvalumab) will be used in combination with Imjudo (tremelimumab) and platinum-based chemotherapy for members who have not received prior systemic therapy for metastatic or Stage IV NSCLC and the tumor is negative for EGFR and ALK, regardless of PD-L1 expression.	
UM ONC_1314	Imfinzi (durvalumab)	Positive change		New FDA Indication
UM ONC_1314	Imfinzi (durvalumab)	Negative change	Add exclusion criteria: D.Dosing exceeds single dose limit of Imfinzi (durvalumab) 10mg/kg (every 2 weeks as a single agent), 20 mg/kg (every 3 weeks when used in combination with chemotherapy), 1500 mg (every 3 weeks when used in combination with chemotherapy), or 1500 mg (every 4 weeks when used as a single agent), or maximum duration of 12 months for NSCLC consolidation therapy. E. For used in combination with Imjudo (tremelimumab): If weight is less than 30 kg, the maximum single dose limit is 20 mg/kg every 4 weeks; for weight 30 kg or more, the maximum single dose limit is 1500 mg every 4 weeks.	Per FDA labeling
UM ONC_1325	Mylotarg (gemtuzumab ozogamicin)	No Clinical Changes	Section IIA3 update: For Health Plans that utilize NCH UM Oncology Clinical Policies, and there is no Health Plan PDL applicable, the Preferred Drug Guidelines shall follow NCH recommended agents/regimens/preferred drugs	Other: NCH prefer drug guidelines
UM ONC_1326	Vyxeos (daunorubicin and cytarabine liposomal)	Positive change	Add inclusion criteria: B.Acute Myeloid Leukemia (AML) 1.Vyxeos (daunorubicin and cytarabine liposomal) may be used for induction and consolidation therapy for adult members aged 60 years or older, with one of the following 5 subtypes of newly diagnosed AM L: therapy-related AML, AML with a history of MDS (myelodysplastic syndrome) with or without prior hypomethylating agent therapy (decitabine or azacitidine), AML with a history of CMMML (chronic myelomonocytic leukemia), and de novo AML with MDS-related cytogenetic abnormalities— <del>who have newly diagnosed, therapy-related AML or AML with MDS-associated cytogenetic abnormalities.</del>	Per Compendia Listing
UM ONC_1326	Vyxeos (daunorubicin and cytarabine liposomal)	Negative change	Add inclusion criteria: B.Acute Myeloid Leukemia (AML) NOTE: Per NCH Policy, Vyxeos (daunorubicin and cytarabine liposomal) is non-Preferred as induction treatment in adult members less than 60 years of age with newly diagnosed AML, except for members with one of the 5 subtypes of AML described in paragraph 1 above. This position is based on the lack of Level 1 evidence ( randomized phase III trials and/or meta-analyses) to show superior outcomes with Vyxeos compared to NCH recommended alternatives.	Per NCH Pathway exclusion
UM ONC_1326	Vyxeos (daunorubicin and cytarabine liposomal)	Negative change	Add exclusion criteria: A.Members without one of the 5 types of AML described in Section B, paragraph 1 above <del>.do not have either therapy-related AML (related to previous cytotoxic chemotherapy and/or radiotherapy, for example, doxorubicin/etoposide) or AML with MDS-related cytogenetic abnormalities.</del>	Per Clinical Trial Analysis/Criteria
UM ONC_1341	Vizimpro (dacomitinib)	No Clinical Changes	Section IIA3 update: For Health Plans that utilize NCH UM Oncology Clinical Policies, and there is no Health Plan PDL applicable, the Preferred Drug Guidelines shall follow NCH recommended agents/regimens/preferred drugs	Other: NCH prefer drug guidelines
UM ONC_1411	Blenrep (belantamab mafodotin-blmf)	Negative change	Remove inclusion criteria: B.Multiple Myeloma 1.The member has relapsed or refractory multiple myeloma and Blenrep (belantamab mafodotin-blmf) will be used as a single agent AND 1.The member is refractory to at least 4 prior lines of therapy including an anti-CD38 antibody (e.g., daratumumab or isatuximab), an Immunomodulatory drug (e.g., lenalidomide or pomalidomide), and a proteasome inhibitor (e.g., bortezomib, ixazomib, or carfilzomib) AND Blenrep (belantamab mafodotin-blmf) is supported upon documentation of an ophthalmic exam prior to and following the administrations of Blenrep (belantamab mafodotin-blmf).	Per GSK announcement
UM ONC_1411	Blenrep (belantamab mafodotin-blmf)	Negative change	Add inclusion criteria: 2.NOTE: Per NCH policy, Blenrep (belantamab mafodotin-blmf) is non-preferred for the treatment of relapsed or refractory multiple myeloma. This recommendation is based on the announcement made by the manufacturer, on November 7, 2022: In the FDA-required confirmatory trial, Blenrep failed to show a significant progression-free survival (PFS) and overall survival (OS) benefit in comparison to pomalidomide and dexamethasone (GSK corporate announcement on theDREAMM-3 clinical trial as referenced below). Please refer to NCH recommended alternatives agents/regimens, including but not limited to regimens at <a href="http://pathways.newcenturyhealth.com">http://pathways.newcenturyhealth.com</a> .	Per GSK announcement
UM ONC_1442	Truseltiq (infigratinib)	Positive change	Remove inclusion criteria: B.Cholangiocarcinoma 2.NOTE: Per NCH Pathway & NCH Policy, Truseltiq (infigratinib) is a non-Preferred drug, the preferred treatment is Pemazyre (pemigatinib) as second line/subsequent therapy for FGFR2 gene fusion or rearrangement positive unresectable/metastatic cholangiocarcinoma. This recommendation is based on the lack of Level 1 evidence (randomized trial and/or meta-analyses) to show superior outcomes with Truseltiq (infigratinib) over Pemazyre (pemigatinib). Please refer to UM ONC_1398 Pemazyre (pemigatinib) policy.	Per NCH Pathway expansion
UM ONC_1442	Truseltiq (infigratinib)	Negative change	Add exclusion criteria: A.B.Lack of molecular testing confirming the presence of an FGFR2 fusion/other rearrangement in the member's cancer	Per FDA labeling
UM ONC_1465	Zynteglo (betibeglogene autotemcel)	N/A	N/A	Archive policy- OOS