Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
UM ONC_1028	Bevacizumab Products [Avastin (bevacizumab)/Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr) Alymsys (bevacizumab maly), Vegzelma (bevacizumab-adcd)	Positive change	Add inclusion criteria: F.Hepatocellular Carcinoma 1.The member has metastatic/inoperable/advanced hepatocellular carcinoma (Child-Pugh Class A or B ~~only~~) a nd bevacizumab/bevacizumab biosimilar will be used in combination with Tecentriq (atezolizumab) for initial therapy.	Compendia Listing
UM ONC_1089	Libtayo (cemiplimab-rwlc)	Negative change	Add exclusion criteria: A.Libtayo (cemiplimab-rwlc) use after disease progression with the same regimen or prior treatment with ~~a PD-1/PDL-1 inhibitor~~ Immune Checkpoint Inhibitor therapy [e.g., Keytruda (pembrolizumab), Opdivo (nivolumab), Tecentriq (atezolizumab)].	Compendia Listing
UM ONC_1132	Rituximab Products	Positive change	Add inclusion criteria: B.CD-20 positive B-Cell Non-Hodgkin's Lymphomas (NHL) and Acute Lymphoblastic Leukemia (B-ALL) d.In members with DLBLC or High-Grade B-Cell Lymphoma (HGBL): Use of R-polatuzunab-CHP (rituximab + polatuzunmab + cyclophosphamide + doxorubicin + prednisone) as first line/initial treatment for an International Prognostic Index (IPI) score of 2 or greater.	New FDA Indication
UM ONC_1180	Immune Globulin (IG)	No Clinical Changes	N/A	N/A
UM ONC_1196	Sprycel (dasatinib)	Positive change	Remove inclusion criteria: B.Acute Lymphoblastic Leukemia (ALL) 1.The member is an adult or pediatric member 1 year of age and older with ~~has~~ Philadelphia Chromosome Positive or BCR-ABL Posiitive ALL ~~with resistance, intolerance, or disease progression on prior therapy with generic imatinib~~ and Sprycel (dasatinib) may be used as monotherapy or in combination with chemotherapy as induction, consolidation, maintenance, or subsequent therapy. C.Chronic Myeloid Leukemia (CML) 1.Sprycel (dasatinib) may be used as a single agent for adult and pediatric members 1 year of age and older with CML (Philadelphia chromosome positive or BCR-ABL positive) as induction, consolidation, maintenance, or subsequent therapy. 2. ~~Sprycel(dasatinib) may be used as a single agent for adult members with CML if there is failure/intolerance/contraindication to generic imatinib.~~	NCH PDL
UM ONC_1196	Sprycel (dasatinib)	Negative change	Remove inclusion criteria: ~~A.Member has not had a trial of generic imatinib for first line therapy of BCR/ABL positive or Philadelphia Chromosome positive CML or ALL.~~	NCH PDL
UM ONC_1196	Sprycel (dasatinib)	Negative change	Add exclusion criteria: D.C.Dosing exceeds single dose limit of Sprycel (dasatinib) 1 ~~4~~80 mg. E.D.Do not exceed 30 (20 mg) tablets/month, 30 (50 mg) tablets/month, 60~~30~~ (70 mg) tablets/month, 30 (80 mg), 30 (100 mg) tablets/month, or 30 (140 mg) tablets/month.	FDA labeling
UM ONC_1199	Tasigna (nilotinib)	Positive change	Remove inclusion criteria: B.Acute Lymphoblastic Leukemia 1.The member has Philadelphia chromosome positive or BCR-ABL Posiitive B-Cell ALL and Tasigna (nilotinib) may be used as a single agent or in combination with chemotherapy as induction, consolidation, maintenance, or subsequent therapy.~~initial/subsequent/maintenance treatment in members who have a contraindication, intolerance, or suboptimal response to prior treatment with generic imatinib.~~ C.Chronic Myeloid Leukemia (CML) 1.The member has CML (Philadelphia chromosome or BCR-ABL1 positive) and Tasigna (nilotinib) may be used as a single agent as initial or subsequent therapy ~~in members who have a contraindication, intolerance, or suboptimal response to prior treatment with generic imatinib.~~	NCH PDL
UM ONC_1206	Xalkori (crizotinib)	Negative change	Add exclusion criteria: C.Dosing exceeds single dose limit of Xalkori (crizotinib) 250 mg (for NSCLC and IMT); 500 mg (for ALCL). D.Treatment exceeds the maximum limit of 120 (250mg) or ~~60~~120 (200 mg) capsules a month.	FDA labeling

UM ONC_1221	Bosulif (bosutinib)	Negative change	Remove 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 as initial or subsequent therapy. ~~and for members with documented history of disease progression, contraindications, or intolerance to generic imatinib AND either [Sprycel (dasatinib) or Tasigna (nilotinib)]. 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.~~	NCH PDL
UM ONC_1221	Bosulif (bosutinib)	Positive change	Add inclusion criteria: C.Acute Lymphoblastic Leukemia 1.The member has Philadelphia chromosome positive or BCR-ABL positive B-Cell ALL and Bosulif (bosutinib) may be used as a single agent or in combination with chemotherapy as induction, consolidation, maintenance, or subsequent therapy.	Compendia Listing
UM ONC_1221	Bosulif (bosutinib)	Positive change	Remove exclusion criteria: ~~A.The member has not had a trial of generic imatinib for first line therapy of BCR/ABL positive or Philadelphia Chromosome positive CML.~~	NCH PDL
UM ONC_1221	Bosulif (bosutinib)	Negative change	Add exclusion criteria: A.The member has disease progression while taking Bosulif (bosutinib). B.Bosulif (bosutinib) is being used on Philadelphia chromosome or BCR-ABL negative CML/ALL.	Compendia Listing
UM ONC_1225	Voraxaze (glucarpidase)	No Clinical Changes	N/A	N/A
UM ONC_1243	Nplate (romiplostim)	Positive change	Remove inclusion criteria: B.Chronic Idiopathic Thrombocytopenic Purpura (ITP) 1.The member is an adult or pediatric member 1 year of age and older with a diagnosis of relapsed/refractory chronic ITP and the initial request is for a platelet count of < 30 x 109/L. AND the member has experienced therapeutic failure of, or has intolerance/contraindications to corticosteroids AND. ~~, immunoglobulin (IVIG), AND/OR rituximab/spl enectomy.~~ 2.The recommended dosing guidelines for Nplate (romiplostim) need to be followed, e.g., a starting dose of 1 mcg/kg, and subsequent increments by 1 mcg/kg/week, if the platelet count remains below 50 x 109/L on the previous lower dose.	NCH PDL
UM ONC_1244	Promacta (eltrombopag)	Positive change	Remove inclusion criteria: B.Chronic Idiopathic Thrombocytopenic Purpura (ITP) 1.The member is an adult or pediatric member 1 year of age and older with a diagnosis of relapsed/refractory chronic ITP with an insufficient response to previous therapies including corticosteroids~~, immunoglobulins (IVIG), and Rituxan (rituximab)/splenectomy~~ AND 2.The member has a platelet count of < 30 x 109/L.	NCH PDL
UM ONC_1244	Promacta (eltrombopag)	Negative change	Add exclusion criteria: C.Treatment exceeds the maximum limit of 30 (12.5 mg), ~~90~~30 (25 mg), 90 (50 mg), 60 (75 mg) tablets/month.	FDA labeling
UM ONC_1261	Cyramza (ramucirumab)	Positive change	Remove inclusion criteria: B.Gastric, Gastroesophageal Junction, and Esophageal Cancers 1.Cyramza (ramucirumab) may be used as monotherapy or in combination with Taxol (paclitaxel) as second line treatment of advanced or metastatic gastric or gastro-esophageal junction adenocarcinoma. ~~2.NOTE: Per NCH Policy, Cyramza (ramucirumab) +/- chemotherapy is Not Approvable for the treatment of Gastric, Esophageal, Gastroesophageal Junction Cancers, and colorectal carcinoma. This Policy Position is based on a large meta-analysis of Randomized Clinical Trials (referenced below) which showed increased serious (including fatal) treatment related toxicities with negligible benefits with the use of Cyramza (ramucirumab) in metastatic solid tumors, compared to NCH recommended alternatives agents/regimens, including but not limited to regimens at http://pathways.newcenturyhealth.com.~~	NCH VBI

UM ONC_1272	Ibrance (palbocidib)	Negative change	Add inclusion criteria: B.Breast Cancer 1.Ibrance (palbociclib) may be used in members with ER/PR positive and HER2 negative recurrent unresectable 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 as first line therapy OR b.In combination with fulvestrant in postmenopausal/premenopausal women treated with ovarian oblation/suppression as subsequent therapy, i f CDK4/6 inhibitor [e.g., Kisqali (ribociclib), Verzenio (abemaciclib)] was not previously used.	FDA labeling
UM ONC_1299	Tecentriq (atezolizumab)	Positive change	Add inclusion criteria: C.Hepatocellular Carcinoma 1.In members with unresectable or metastatic hepatocellular carcinoma AND preserved liver function (Child-Pugh Class A or B), who have not received prior therapy with a checkpoint inhibitor, e.g., Keytruda (pembrolizumab) or Opdivo (nivolumab). Tecentriq (atezolizumab) may be used in combination with Avastin (bevacizumab)/bevacizumab biosimilar as first line therapy in the metastatic setting.	Compendia Listing
UM ONC_1303	Xermelo (telotristat ethyl)	No Clinical Changes	N/A	N/A
UM ONC_1310	Kisqali (ribociclib)	Negative change	Add inclusion criteria: B.Breast Cancer ~~1.The member has recurrent or metastatic breast cancer and Kisqali (ribociclib) will be used in combination with an aromatase inhibitor [i.e., Femara (letrozole), Arimidex (anastrozole), or Aromasin (exemestane)] or Faslodex (fulvestrant) and ALL the following:~~ ~~a.Confirmed ER/PR positive and HER2 negative breast cancer AND~~ ~~a.Member is postmenopausal OR if member is premenopausal, the member is also receiving ovarian ablation/suppression, e.g., with leuprolide.~~ 1.Kisqali (ribociclib) may be used in members with ER/PR positive and HER2 negative recurrent unresectable or metastatic breast cancer as follows: a.In combination with an aromatase inhibitor [i.e., Arimidex (anastrozole), Femara (letrozole), Aromasin (exemestane)] in postmenopausal or premenopausal women treated with ovarian oblation/suppression as first line therapy OR b.In combination with Faslodex (fulvestrant) in postmenopausal or premenopausal women treated with ovarian oblation/suppression as subsequent therapy, if CDK4/6 inhibitor [e.g., Ibrance (Palbociclib), Verzenio (abemaciclib)] was not previously used..	Compendia Listing
UM ONC_1311	Lonsurf (trifluridine/tipiracil)		N/A	N/A
UM ONC_1316	Nerlynx (meratinib)	Negative change	Add inclusion criteria: B.Breast Cancer 1.The member has early stage (stages I, II, and III) hormone receptor positive, HER2 positive breast cancer, and Nerlynx (neratinib) is being used as a single agent following completion of adjuvant trastuzumab-containing therapy OR 2.Nerlynx (neratinib) is being used in combination with Xeloda (capecitabine) in members with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 based regimens in the metastatic setting.	FDA labeling
UM ONC_1316	Nerlynx (meratinib)	Negative change	Add exclusion criteria: D.Treatment exceeds the maximum limit of 180 (40 mg) tablets/month for adjuvant treatment; 126 (40 mg) tablets/month for advanced or metastatic treatment.	FDA labeling
UM ONC_1323	Idhifa (enasidenib)	Negative change	Remove inclusion criteria: B.Acute Myeloid Leukemia (AML) with Positive IDH-2 Mutation 1.The member has a confirmed diagnosed of IDH-2 mutation positive AML (confirmed with any FDA approved test) and Idhifa (enasidenib) may be used either as a single agent for relapsed or refractory disease OR 2.Idhifa(enasidenib) may be used as first line therapy in IDH2 mutation positive AML ~~in combination with either azacitidine or decitabine~~ as a single agent, in a member who is not a suitable candidate for standard induction/consolidation chemotherapy.	Compendia Listing
UM ONC_1323	Idhifa (enasidenib)	Positive change	Remove exclusion criteria: A.Idhifa (enasidenib) is being used after disease progression with the Idhifa . ~~or an Idhifa-containing regimen.~~	Compendia Listing

UM ONC_1323	Idhifa (enasidenib)	Negative change	Add exclusion criteria: B.Lack of documentation of IDH-2 mutation positivity.	Compendia Listing
UM ONC_1328	Verzenio (abemaciclib)	Negative change	Add inclusion criteria: B.Breast Cancer 2.The member has recurrent or metastatic breast cancer and of ALL the following criteria: B a.Confirmed ER/PR positive and HER2 negative breast cancer AND 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 [i.e., Arimidex (anastrozole), Femara (letrozole), Aromasin (exemestane)] as first line therapy for recurrent unresectable/metastatic disease OR ii.In combination with Faslodex (fulvestrant) ~~as first line or~~ as subsequent therapy if CDK4/6 inhibitor [e.g., Kisqali (ribociclib), Ibrance (palbociclib)] was not previously used OR iii.As a single agent for disease progression following endocrine therapy (that did not include a CDK4/6 inhibitor) AND chemotherapy for metastatic disease.	FDA labeling
UM ONC_1333	Erleada (apalutamide)	Negative change	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 b.In members with metastatic (M1) castration sensitive prostate cancer.	Compendia Listing
UM ONC_1340	Tibsovo (ivosidenib)	No Clinical Changes	N/A	N/A
UM ONC_1345	Tavalisse (fostamatinib)	Positive change	Remove inclusion criteria: B.Immune Thrombocytopenic Purpura (ITP) 1.Tavalisse (fostamatinib) may be used as a single agent, or in combination with one concomitant ITP medication (limited to one of the following: corticosteroids < 20 mg prednisone/equivalent daily, azathioprine, or danazol) when the following criteria have been satisfied: a.The member has relapsed/refractory chronic ITP AND b.For initial request: There has been an insufficient response (defined by failure of platelet count to increase and stay above 30 x 109/L) to prior therapies including corticosteroids~~, IVIG, splenectomy/Rituxan,~~ and~~/or~~ a Thrombopoietin Receptor Agonist (romiplostim, eltrombopag or avatrombopag) AND a platelet count ≤ 30 x 109/L prior to start of therapy OR c.For continuation request: The member did not achieved a rise in Platelet counts or the member ~~continues to~~ did not experience significant bleeding any time during treatment with Tavalisse (fostamatinib).	NCH PDL
UM ONC_1362	Polivy (polatuzumab vedotin)	Positive change	Add inclusion criteria: B.Diffuse Large B-Cell Lymphoma (DLBCL) ~~1.The member has relapsed/refractory DLBCL and Polivy (polatuzumab vedotin) may be used as a single agent or in combination with bendamustine with or without rituximab/rituximab biosimilars AND~~ ~~2.The member is not eligible for hematopoietic stem cell transplant or has relapsed after hematopoietic stem cell transplant AND~~ ~~3.Has failed at least one or more lines of prior therapies for DLBCL.~~ 1.Polivy (polatuzumab vedotin) may be used as follows: a.In members with DLBLC or High-Grade B-Cell Lymphoma (HGBL): In combination with R-CHP (rituximab + cyclophosphamide + doxorubicin + prednisone) as first line/initial treatment for an International Prognostic Index (IPI) score of 2 or greater OR b.In members with DLBCL: As a single agent or in combination with bendamustine, with or without rituximab/rituximab biosimilars as second line or subsequent therapy.	New FDA Indication
UM ONC_1362	Polivy (polatuzumab vedotin)	Negative change	Add exclusion criteria: A.Use of Polivy (polatuzumab vedotin) after disease progression with the same regimen or prior Polivy (polatuzumab vedotin) or bendamustine unless therapy was completed more than a year ago.	FDA labeling

UM ONC_1412	Monjuvi (tafasitamab-cxix)	Negative change	Add inclusion criteria: B.Diffuse Large B Cell Lymphoma (DLBCL) 1.Monjuvi (tafasitamab-cxix) may be used in combination with Revlimid (lenalidomide) up to 12 cycles with further continuation as monotherapy for members with a.CD-19 expression on lymphoma cells confirmed by any standard test AND b.Relapsed/refractory DLBCL (including transformation from an indolent lymphoma) who are not candidates for a stem cell transplant or have failed a prior stem cell transplant AND c.Receipt of 1-3 prior regimens including a chemoimmunotherapy regimen containing an anti- CD20-targeted therapy (e.g., rituximab, obinituzumab).	FDA labeling
UM ONC_1415	Jelmyto (mitomycin for pyelocalyceal installation)	Negative change	Remove 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 and ~~or~~ in me mbers who are not candidates for endoscopic/surgical intervention as primary treatment or for treatment of recurrent disease.	Compendia Listing
UM ONC_1434	Zynlonta (loncastuzimab tesirine-lpyl)	Negative change	Add exclusion criteria: A.Zynlonta (loncastuzimab tesirine-lpyl) is being used on or after disease progression with the same regimen. B.Dosing exceeds single dose limit of Zynlonta (loncastuzimab tesirine-lpyl) 0.15 mg/kg (the first 2 cycles); 0.075 mg/kg (cycle 3 and beyond).	FDA labeling
UM ONC_1443	Mozobil (plerixafor)	Positive change	Remove inclusion criteria: B.Peripheral Blood Stem Cell (PBSC) Mobilization 1.Mozobil (plerixafor) may be used as a hematopoietic stem cell mobilizer ~~in combination with a short acting MGF (NCH Preferred is Zarxio or Granix) on day 4-5 of MGF +/- chemotherapy mobilization~~ in members with non-Hodgkin's lymphoma or multiple myeloma undergoing ~~subsequent~~ autologous transplantation.	Compendia Listing
UM ONC_1446	Welireg (belzutifan)	No Clinical Changes	N/A	N/A
UM ONC_1448	Ferriprox (deferiprone)	Negative change	Remove inclusion criteria: B.A.Transfusional Iron Overload 1.Ferriprox (deferiprone) may used as monotherapy, or in combination with SQ deferoxamine, in adult or pediatric members 8 years and older with iron overload due to transfusion dependent thalassemia, sickle cell disease or other anemias ~~(or other anemias with iron overload) if the member has a documented contraindication, intolerance, or failure to generic deferasirox.~~ AND 2.The member failed prior chelation therapy and has a serum ferritin greater than 2,500 mcg/L.	FDA labeling