Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
New	Zynyz (retifanlimab-dlwr)	N/A	N/A	N/A
UM ONC_1041	LHRH agonists and antagonist	Negative change	Remove inclusion criteria: ~~B.Breast Cancer~~ ~~1.Per NCH Policy, LHRH analogs are Approvable for ovarian suppression in breast cancer with the exceptions listed in the NOTE below.~~ ~~2.NOTE 1: Per NCH Policy, the following LHRH analog products are not approvable for use in breast cancer:~~ ~~a.Lupron Depot (J1950 leuprolide acetate 3.75 mg or 11.25 mg)~~ ~~b.Lutrate Depot (J1954 leuprorelin acetate 22.5 mg)~~ ~~c.Zoladex (J9202 goserelin acetate).~~ ~~d.Camcevi SC Depot (J1952 leuprolide mesylate)~~ ~~e.Firmagon (J9155 degarelix)~~ ~~f.Orgovyx (J8999 relugolix).~~ ~~3.NOTE 2: The above Policy Positions for Not Approvable drugs are based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) showing superior outcomes with one LHRH analog or one dosage form over another in the treatment of breast cancer. Please refer to NCH alternative agents/regimens recommended by NCH, including but not limited to regimens available at http://pathways.newcenturyhealth.com.~~ ~~C.Fertility Preservation in Women Undergoing Cytotoxic Chemotherapy~~ ~~1.Per NCH Policy, LHRH analogs are Approvable for members receiving fertility-impairing anti-cancer therapy who desire fertility preservation, with the exceptions listed in the NOTE below.~~ ~~2.NOTE 1: Per NCH Policy, the following LHRH analog products are Not Approvable for fertility preservation:~~ ~~a.Lupron Depot (J1950 leuprolide acetate 3.75 mg or 11.25 mg)~~ ~~b.Lutrate Depot (J1954 leuprorelin acetate 22.5 mg)~~ ~~c.Zoladex (J9202 goserelin acetate)~~ ~~d.Camcevi SC Depot (J1952 leuprolide mesylate)~~ ~~e.Firmagon (J9155 degarelix)~~ ~~f.Orgovyx (J8999 relugolix).~~ ~~3.An exception would be made to the above policy if the fertility preservation physician/specialist requests a specific agent and/or a specific dosage form.~~ ~~4.NOTE 2: The above Policy Positions for the Not Approvable drugs are based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) showing superior outcomes with one LHRH analog over another for fertility preservation. Please refer to NCH alternative agents/regimens recommended by NCH, including but not limited to regimens available at http://pathways.newcenturyhealth.com.~~	NCH PDL
UM ONC_1041	LHRH agonists and antagonist	Negative change	Add inclusion criteria: B.Breast Cancer 1.Luteinizing Hormone Releasing Hormone (LHRH) analogs (any of the following product) may be used in combination with endocrine therapy (e.g., tamoxifen, aromatase inhibitors) for ovarian suppression in premenopausal women and in men with ER/PR positive breast cancer as adjuvant therapy or as therapy for recurrent/metastatic disease. a.Eligard SC/Lupron IM Depot (J9217 leuprolide acetate 7.5 mg monthly, 22.5 mg every 3 months, 30 mg every 4 months, 45 mg every 6 months) b.Lutrate IM Depot (J1954 leuprolide acetate 22.5 mg every 3 months) c.Camcevi SC Kit (J1952 leuprolide mesylate 46 mg every 6 months) d.Trelstar IM Depot (J3315 triptorelin pamoate 3.75 mg monthly, 11.25 mg every 3 months, and 22.5 mg every 6 months) e.Zoladex SC Implant (J9202 goserelin acetate 3.6 mg monthly and 10.8 every 3 months) C.Fertility Preservation in Women Undergoing Cytotoxic Chemotherapy 1.For women undergoing cytotoxic chemotherapy, Luteinizing Hormone Releasing Hormone (LHRH) analogs (any of the following product) may be used in conjunction with fertility preservation methods. a.Eligard SC/Lupron IM Depot (J9217 leuprolide acetate 7.5 mg monthly, 22.5 mg every 3 months, 30 mg every 4 months, 45 mg every 6 months) b.Lutrate IM Depot (J1954 leuprolide acetate 22.5 mg every 3 months) c.Camcevi SC Kit (J1952 leuprolide mesylate 46 mg every 6 months) d.Trelstar IM Depot (J3315 triptorelin pamoate 3.75 mg monthly, 11.25 mg every 3 months, and 22.5 mg every 6 months) e.Zoladex SC Implant (J9202 goserelin acetate 3.6 mg monthly and 10.8 every 3 months). D.Prostate Cancer 1.Luteinizing Hormone Releasing Hormone (LHRH) analogs (any of the following product) may be used as a single agent or in combination with an antiandrogen with or without chemotherapy for the treatment of castrate sensitive or castrate resistant M0 or M1 prostate cancer. a.Eligard SC/Lupron IM Depot (J9217 leuprolide acetate 7.5 mg monthly, 22.5 mg every 3 months, 30 mg every 4 months, 45 mg every 6 months) b.Lutrate IM Depot (J1954 leuprolide acetate 22.5 mg every 3 months) c.Camcevi SC Kit (J1952 leuprolide mesylate 46 mg every 6 months) d.Trelstar IM Depot (J3315 triptorelin pamoate 3.75 mg monthly, 11.25 mg every 3 months, and 22.5 mg every 6 months) e.Zoladex SC Implant (J9202 goserelin acetate 3.6 mg monthly and 10.8 every 3 months) f.Orgovyx (J8999 relugolix 360 mg on day 1 followed by 120 mg oral daily)	NCH PDL
UM ONC_1041	LHRH agonists and antagonist	Positive change	Remove exclusion criteria: ~~A.Zoladex (goserelin), Trelstar (triptorelin), or Lupron Depot/Lutrate Depot (leuprolide acetate) is being used in postmenopausal female member.~~ ~~B.Zoladex (goserelin), Trelstar (triptorelin), or Lupron/Lutrate (Leuprolide) is being used in member with hormone receptor negative (ER and/or PR negative) breast cancer, except when being used for fertility preservation or for other non-cancer indications.~~ ~~C.Camcevi SC Depot (J1952 leuprolide mesylate), Firmagon (J9155 degarelix), or Orgovyx (J8999 relugolix) is being used in members with breast cancer or for fertility preservation in women undergoing cytotoxic chemotherapy.~~	NCH PDL
UM ONC_1179	Abraxane (nab-paclitaxel)	No Clinical Changes	NCH VBI language change	NCH VBP

UM ONC_1181	Iron Products	Positive change	Remove inclusion criteria: B.Iron Deficiency 1.The member has iron deficiency with or without anemia with the presence of any ONE or MORE of the following: a.Serum ferritin less than 30 ng/mL b.Transferrin saturation (TSAT) less than 20% c.Absence of stainable iron in the bone marrow d.Improvement of anemia with iron replacement therapy (oral or parenteral) OR 2.The member is receiving (or has received within the last 8 weeks) myelosuppressive chemotherapy AND has chemotherapy induced anemia defined as a Hgb less than 10 g/dL or HCT less than 30 (levels obtained within the last 4 weeks) AND iron products may be used with or without concomitant ESA therapy. Acceptable labs in this situation include a Ferritin less than 30 ng/mL and/or a TSAT (transferrin saturation) of less than 20% within the last 12 months. OR 3.The member has anemia of chronic kidney disease defined by a GFR of less than 60 mL/min AND a Hgb of less than 10 gm/dL or HCT less than 30 (levels obtained within the last 4 weeks). Parenteral iron products may be used with or without concomitant ESA therapy. Acceptable labs in this situation include a Ferritin of less than 30 ng/mL and/or a TSAT (transferrin saturation) of less than 20%. ~~4.NOTE: Per NCH policy, the following products are not approvable for the treatment of iron deficiency. The above Policy Position is based on a lack of level 1 evidence (randomized trials and/or meta-analyses) supporting superior outcomes for any Not Approvable iron replacement products over the Approvable products. The use of a Not Approvable product is supported, per NCH policy, if the member has a history of hypersensitivity reaction or other adverse effects from the Approvable product(s):~~ ~~a.Accrufer (ferric maltol) is a not approvable oral iron product. The Approvable oral ferrous iron products are, but not limited to, ferrous sulfate, ferrous gluconate, and/or ferrous fumarate.~~ ~~b.Monoferric (ferric derisomaltose) and Injectafer (ferric carboxymaltose) are not approvable parenteral iron products. The Approvable parenteral iron products are Infed (iron dextran), Venofer (iron sucrose), Ferrlecit (ferric gluconate), and/or Feraheme (ferumoxytol).~~	NCH PDL
UM ONC_1181	Iron Products	Positive change	Add inclusion criteria: B.Iron Deficiency 1.The member has iron deficiency with or without anemia with the presence of any ONE or MORE of the following: a.Serum ferritin less than 30 ng/mL b.Transferrin saturation (TSAT) less than 20% c.Absence of stainable iron in the bone marrow d.Improvement of anemia with iron replacement therapy (oral or parenteral) OR 2.The member is receiving (or has received within the last 8 weeks) myelosuppressive chemotherapy AND has chemotherapy induced anemia defined as a Hgb less than 10 g/dL or HCT less than 30 (levels obtained within the last 4 weeks) AND iron products may be used with or without concomitant ESA therapy. Acceptable labs in this situation include a Ferritin less than 30 ng/mL and/or a TSAT (transferrin saturation) of less than 20% within the last 12 months. OR 3.The member has anemia of chronic kidney disease defined by a GFR of less than 60 mL/min AND a Hgb of less than 10 gm/dL or HCT less than 30 (levels obtained within the last 4 weeks). Parenteral iron products may be used with or without concomitant ESA therapy. Acceptable labs in this situation include a Ferritin of less than 30 ng/mL and/or a TSAT (transferrin saturation) of less than 20%. 4.NOTE: Per NCH Policy, prior to using intravenous iron products for the above indications, the member has documentation of failure or intolerance to oral iron products, An exception to the above recommendation is for members with anemia of chronic kidney disease.	NCH PDL
UM ONC_1190	Bone Modifying Agents (Aredia, Zometa, X	Positive change	Remove inclusion criteria: B.Breast Cancer 1.The member has non-metastatic breast cancer and Zometa (zoledronic acid) is being used for the prevention or treatment of osteoporosis when the member is receiving adjuvant aromatase inhibitor therapy and/or ovarian suppression/ablation OR 2.Zometa (zoledronic acid) is being used as a part of the adjuvant therapy regimen in combination with adjuvant endocrine treatment for early breast cancer in a postmenopausal woman or a premenopausal woman on ovarian suppression/ablation. NOTE: Typical dosing in this setting is Zometa (zoledronic acid) 4 mg iv every 6 months. ~~3.NOTE: Per NCH Policy, Xgeva/Prolia (denosumab) are not approvable f or members with breast cancer. Xgeva/Prolia (denosumab) would be Approvable for the above indications if the member has a documented intolerance/contraindications to Zometa (zoledronic acid) for example renal impairment and a CrCl of less than 30 mL/min. Please refer to NCH alternative agents/regimens recommended by NCH, including but not limited to regimens available at http://pathways.newcenturyhealth.com.~~ C.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) will be used as a single agent for unresectable localized disease OR for metastatic disease. D.Hypercalcemia of Malignancy 1.Zometa (zoledronic acid) or Aredia (pamidronate) is being used in conjunction with hydration for hypercalcemia as defined as a corrected calcium of greater than or equal to 12 mg/dL (corrected for albumin level). The following formula is used to calculate the corrected calcium level: a.Corrected Calcium (mg/dL) = Calcium + 0.8 x (4 – patient Albumin). ~~2.NOTE: Per NCH Policy, Xgeva/Prolia (denosumab) are not approvable for Hypercalcemia of malignancy. Exception: Member with hypercalcemia of malignancy and the member has a documented intolerance/contraindications to bisphosphonates (e.g., pamidronate, zoledronic acid), for example renal impairment and a CrCl of less than 30 mL/min.~~ E.Multiple Myeloma 1.The member has multiple myeloma and Zometa (zoledronic acid) or Aredia (pamidronate) is being used with or without anti-myeloma therapy. ~~2.NOTE: Per NCH Policy, Xgeva/Prolia (denosumab) are not approvable for multiple myeloma. Xgeva/Prolia (denosumab) would be Approvable for members with Multiple Myeloma if the member has a documented intolerance/contraindications to bisphosphonates (e.g., pamidronate, zoledronic acid), for example renal impairment and a CrCl of less than 30 mL/min. Please refer to NCH alternative agents/regimens recommended by NCH, including but not limited to regimens available at http://pathways.newcenturyhealth.com.~~ F.Prostate Cancer	NCH PDL
UM ONC_1193	Revlimid (lenalidomide)	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1194	Nexavar (sorafenib)	No Clinical Changes	NCH VBI language change	NCH VBP

UM ONC_1199	Tasigna (nilotinib)	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1200	Torisel (temsrolimus)	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1201	Yervoy (ipilimumab)	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1203	Adcetris (brentiximab)	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1207	Zelboraf (vemurafenib)	Positive change	Remove inclusion criteria: B.Malignant Melanoma 1.Zelboraf (vemurafenib) may be used in combination with cobimetinib or as a single agent (if combination therapy is contraindicated) in a member with BRAF V600E mutation positive metastatic/recurrent/unresectable malignant melanoma for ONE of the following: a.First line therapy b.Second-line or subsequent line therapy. ~~if the member has not been treated previously with Zelboraf (vemurafenib) + Cotellic (cobimetinib) OR another combination of a BRAF inhibitor + MEK inhibitor.~~ 1.b.NOTE: Per NCH Policy, [Cotellic (cobimetinib) + Zelboraf (vemurafenib) + Tecentriq (atezolizumab)] is ~~Not Approvable~~ not supported by NCH Policy for the treatment of metastatic, recurrent, or unresectable BRAF V600E or V600K mutation positive malignant melanoma. This Policy Position is based on the OS results of the IMspire150 trial. This trial showed no difference in Overall Survival with the above 3-drug combination compared to Cotellic (cobimetinib) + Zelboraf (vemurafenib) regimen. Please see attached references including the updated survival results from the IMspire150 trial. Please refer to NCH alternative agents/regimens recommended by NCH, including but not limited to regimens available at http://pathways.newcenturyhealth.com.	NCH PDL
UM ONC_1215	Treanda/Bendeka/Belrapzo (bendamustine	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1218	Provenge (sipuleucel-T)	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1223	Inlyta (axitinib)	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1224	Kyprolis (carfilzomib)	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1226	Zaltrap (ziv-aflibercept)	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1234	Zevalin (ibritumomab tiuxetan)	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1235	Doxil (liposomal doxorubicin)	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1249	Mekinist (trametinib)	Positive change	Add inclusion criteria: B.Low Grade Glioma 1.Mekinist (trametinib) may be used in combination with Tafinlar (dabrafenib) in members 1 year of age and older with low grade glioma with a BRAF V600E mutation.	New FDA Indication
UM ONC_1250	Tafinlar (dabrafenib)	Positive change	Add inclusion criteria: B.Low Grade Glioma 1.Tafinlar (dabrafenib)may be used in combination with Mekinist (trametinib) in members 1 year of age and older with low grade glioma with a BRAF V600E mutation.	New FDA Indication
UM ONC_1259	Gazyva (obinutuzumab)	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1261	Cyramza (ramucirumab)	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1262	Imbruvica (ibrutinib)	Negative change	Remove inclusion criteria: C.Mantle Cell Lymphoma (MCL) and Marginal Zone Lymphoma (MZL) ~~1.Imbruvica (ibrutinib) may be used in a member with relapsed or refractory MCL that has failed or has progressed on first line chemotherapy/chemo-immunotherapy AND~~ ~~1.Imbruvica (ibrutinib) will be used as a single agent or in combination with rituximab/rituximab biosimilar product.~~ ~~2.NOTE: Per NCH Policy, [Ibrutinib + Lenalidomide + Rituximab] and [Ibrutinib + Venetoclax] are Not Approvable for the treatment of MCL. This Policy Position is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with the above regimens compared to NCH recommended alternatives agents/regimens, including but not limited to regimens at http://pathways.newcenturyhealth.com.~~ 3.NOTE: Imbruvica (ibrutinib) is not supported by NCH Policy for the treatment of patients with relapsed/refractory mantle cell lymphoma (MCL) and marginal zone lymphoma (MZL). This policy position is based on the manufacturer's voluntary withdrawal of Imbruvica and FDA guidance following confirmatory study results. The results showed no overall survival and progression free survival advantage in MCL and MZL, respectively. Please refer to the NCH recommended alternative agents/regimens, including but not limited to regimens available at http://pathways.newcenturyhealth.com. ~~D.Nodal & Extra-Nodal Marginal Zone Lymphoma & Splenic Marginal Zone Lymphoma~~ ~~1.The member has relapsed or refractory nodal/extra-nodal/splenic marginal zone lymphoma AND~~ ~~1.Imbruvica (ibrutinib) will be used as a single agent as second-line or subsequent therapy in members who have received an anti-CD20 based therapy [e.g., rituximab, obinutuzumab).~~	Manufacturer Withdrawal
UM ONC_1262	Imbruvica (ibrutinib)	Positive change	Remove exclusion criteria: C.Dosing exceeds single dose limit of Imbruvica (ibrutinib) ~~560 mg (for MCL and MZL) or~~ 420 mg (for CLL/SLL, and WM).	FDA labeling
UM ONC_1263	Keytruda (pembrolizumab)	Negative change	Add exclusion criteria: C.Dosing exceeds single dose limit of Keytruda (pembrolizumab) 200 mg every 3 weeks or 400 mg every 6 weeks,	FDA labeling
UM ONC_1264	Zydelig (idelalisib)	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1273	Lynparza (olaparib)	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1274	Opdivo (nivolumab)	No Clinical Changes	NCH VBI language change	NCH VBP

UM ONC_1279	Cotellic (cobimetinib)	Positive change	Remove inclusion criteria: B.Malignant Melanoma 1.Cotellic (cobimetinib) may be used in combination with Zelboraf (vemurafenib) in members with BRAF V600E or V600K mutation positive metastatic, recurrent, or unresectable malignant melanoma in any of the following clinical scenarios: a.First line therapy for metastatic or unresectable disease OR b.Second-line or subsequent therapy for metastatic or unresectable disease. ~~if the member has not been treated previously with Cotellic (cobimetinib) + Zelboraf (vemurafenib) OR another combination of a BRAF inhibitor + MEK inhibitor.~~ c.b.NOTE: Per NCH Policy, [Cotellic (cobimetinib) + Zelboraf (vemurafenib) + Tecentriq (atezolizumab)] is ~~Not Approvable~~ not supported per NCH Policy for the treatment of metastatic, recurrent, or unresectable BRAF V600E or V600K mutation positive malignant melanoma. This Policy Position is based on the overall survival results of the IMspire150 trial. This trial showed no difference in Overall Survival with the above 3-drug combination compared to Cotellic (cobimetinib) + Zelboraf (vemurafenib) regimen. Please refer to NCH alternative agents/regimens recommended by NCH, including but not limited to regimens available at http://pathways.newcenturyhealth.com.	NCH PDL
UM ONC_1280	Darzalex and Darzalex Faspro (daratumuma	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1282	Imlygic (Talimogene Laherparepvec)	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1284	Ninlaro (ixazomib)	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1287	Tagrisso (osimertinib)	Positive change	Add inclusion criteria: B.Non-Small Cell Lung Cancer (NSCLC) 1.The member has recurrent or metastatic, EGFR positive NSCLC (Exon 19 deletion or Exon 21 L858R point mutation) ~~NSCLC~~, and Tagrisso (osimertinib) is being used as a single agent for first line therapy OR 2.As subsequent therapy for EGFR T790M mutation-positive disease following progression on Tarceva (erlotinib), Gilotrif (afatinib), Iressa (gefitinib), or Vizimpro (dacomitinib) OR 3.The member has EGFR positive (Exon 19 deletion or Exon 21 L858R point mutation), stage ~~II-IIIA~~ IB-IIIA Non-Small Cell Lung Cancer, that has been completely resected and Tagrisso (osimertinib) is being used as adjuvant therapy (with or without adjuvant chemotherapy). Maximum duration of such adjuvant therapy with Tagrisso (osimertinib) is up to 3 years.	FDA labeling
UM ONC_1287	Tagrisso (osimertinib)	Negative change	Add exclusion criteria: A.Concurrent use with anti-cancer therapy. Use with adjuvant chemotherapy for stage ~~II-IIIA~~ IB-IIIA completely resected, EGFR+ NSCLC is allowed. B.Dosing exceeds single dose limit of 80 mg. C.Member has an uncommon EGFR Exon 20 insertion mutation. D. Lack of documentation for EGFR mutation confirmed by a standard test.	FDA labeling
UM ONC_1290	Yondelis (trabectedin)	Positive 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 or in combination with doxorubicin as first line or subsequent therapy. ~~following disease progression with an anthracycline-based chemotherapy, unless there is a contraindication/intolerance with prior anthracycline based therapy.~~	Compendia Listing
UM ONC_1297	Venclexta (venetoclax)	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1299	Tecentriq (atezolizumab)	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1301	Rubraca (rucaparib)	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1306	Bavencio (avelumab)	Negative change	Remove inclusion criteria: C.Renal Cell Carcinoma (RCC) 1. ~~Bavencio (avelumab) may be used in combination with Inlyta (axitinib) as first line therapy in members with advanced/metastatic RCC.~~ 2.NOTE: Per NCH Policy, Bavencio (avelumab) + Inlyta (axitinib) is ~~not approvable~~ supported by NCH Policy for subsequent treatment of advanced or metastatic renal cell carcinoma. This ~~recommendation~~ policy position is based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) to show superior outcomes with Bavencio (avelumab) + Inlyta (axitinib) in the subsequent line setting compared to NCH recommended alternatives agents/regimens, including but not limited to regimens at http://pathways.newcenturyhealth.com.	NCH VBP
UM ONC_1307	Zejula (niraparib)	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1313	Alunbrig (brigatinib)	Negative change	Add exclusion criteria: A.Disease progression while receiving Alunbrig (brigatinib) therapy. B.Concurrent use with ~~chemotherapy~~ other anticancer therapies. C.Lack of documentation for ALK rearrangement confirmed by a standard test.	FDA labeling
UM ONC_1315	Rydapt (midostaurin)	Negative change	Add exclusion criteria: A.Disease progression on Rydapt (midostaurin) or another FLT-3 inhibitor, e.g., Xospata (gilteritinib). B.Dosing exceeds single dose limit of Rydapt (midostaurin) 50 mg (for AML) or 100 mg (for ASM, MCL, or SM-AHN). C.Lack of documented FLT3 mutation on leukemia cells (applies to AML). D.Treatment exceeds the maximum limit of 240 (25 mg) ~~tablets~~ capsules/month for ASM, MCL, or SM-AHN) and 120 (25 mg) capsules/month for AML.	FDA labeling
UM ONC_1325	Mylotarg (gemtuzumab ozogamicin)	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1326	Vyxeos (daunorubicin and cytarabine liposo	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1331	Calquence (acalbrutinib)	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1342	Azedra (iobenguane I-131)	Positive change	Remove inclusion criteria: B.Pheochromocytoma/Paraganglioma 1.The member is an adult or pediatric member 12 years of age and older who has unresectable, locally advanced, or metastatic pheochromocytoma or paraganglioma AND 2.Azedra (iobenguane I-131) is being used as a primary treatment for member with a positive MIBG (meta-iodobenzylguanidine) scan. ~~AND~~ ~~3.The member is not a candidate for or has failed prior chemotherapy and/or surgery.~~	FDA labeling

UM ONC_1345	Tavalisse (fostamatinib)	Negative change	Add 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).	FDA labeling
UM ONC_1345	Tavalisse (fostamatinib)	Negative change	Add exclusion criteria: A.The member did not achieve a rise in platelet counts or the member experienced significant bleeding at any time during treatment with Tavalisse (fostamatinib).	FDA labeling
UM ONC_1349	Talzenna (talazoparib)	Positive change	Add inclusion criteria: B.Breast Cancer 1.Talzenna (talazoparib) may be used as monotherapy for members with HER2-negative and BRCA 1/2-germline mutated locally advanced or metastatic breast cancer.	FDA labeling
UM ONC_1349	Talzenna (talazoparib)	Positive change	Remove inclusion criteria: B.Breast Cancer ~~2.NOTE: Per NCH policy, Talzenna (talazoparib) is Not Approvable for use when a PARP inhibitor is indicated for use in germline or somatic BRCA1/2 mutation positive metastatic breast cancer. The approvable PARP inhibitor is Lynparza (Olaparib) for the above clinical setting unless there is an intolerance or a contraindication to Lynparza (Olaparib). This Policy Position is based on data from the phase III EMBRACA trial in which Talzenna (talazoparib) did not show a statistically significant overall survival benefit for patients with metastatic breast cancer with a germline BRCA 1/2 mutation, in addition to a lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes for one PARP inhibitor over another. Please refer to NCH alternative agents/regimens recommended by NCH, including but not limited to regimens available at http://pathways.newcenturyhealth.com.~~	FDA labeling
UM ONC_1349	Talzenna (talazoparib)	Negative change	Add exclusion criteria: B.Lack of documentation for the detection of HER2-negative and BRCA 1/2-germline mutation prior to initiation of treatment. C. Concurrent use with other ~~chemotherapy~~ anticancer therapies.	FDA labeling
UM ONC_1356	Elzonris (tagraxofusp)	Negative change	Add inclusion criteria: B.Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) 1.The member has BPDCN and Elzonris (tagraxofusp) will be used as a single agent in adults and pediatric ~~patients~~ members 2 years and older for induction/continuation treatment until disease progression of newly diagnosed/relapsed/refractory disease (if not used previously).	FDA labeling
UM ONC_1364	Turalio (pexidartinib)	Positive change	Add inclusion criteria: B.Tenosynovial Giant Cell Tumor (TGCT) 1.The member has symptomatic TGCT associated with severe morbidity/functional limitations not amenable to improvement with surgery, or ~~patient~~ member is not a surgical candidate AND 2.Turalio (pexidartinib) will be used as a single agent for non-~~malignant~~ metastatic TGCT.	FDA labeling
UM ONC_1364	Turalio (pexidartinib)	Positive change	Add exclusion criteria: D.Treatment exceeds the maximum limit of 120 (200 mg) ~~tablets~~ capsules/month.	FDA labeling
UM ONC_1365	Xpovio (selinexor)	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1366	Inrebic (fedratinib)	Positive change	Remove inclusion criteria: B.Myelofibrosis (MF) 1.Inrebic (fedratinib) may be used as a single agent in a member with primary myelofibrosis or secondary myelofibrosis (e.g., post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis), ~~AND~~ a platelet count of greater than or equal to 50 × 109/L prior to start of treatment, AND the member has splenomegaly. ~~The member has splenomegaly AND~~ ~~2.The member has intermediate (2 prognostic factors) or high-risk (3 or more prognostic factors) myelofibrosis. The prognostic factors include the following:~~ ~~a.Age > 65 years~~ ~~b.Hemoglobin < 10 g/dL~~ ~~c.Leukocyte > 25 x 109/L~~ ~~d.Circulating blasts ≥ 1%~~ ~~e.Platelet count < 100 x 109LL~~ ~~f.RBC transfusion need~~ ~~g.Unfavorable karyotype +8, -7/7q-, i(17q), inv(3), -5/5q-, 12p-, 11q23.~~ ~~3.NOTE: Per NCH Policy, Inrebic (fedratinib) is Not Approvable for the treatment of primary myelofibrosis or secondary myelofibrosis (e.g., post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis); an exception can be made if the member is intolerant to/has a contraindication to/has experienced disease progression on Jakafi (Ruxolitinib). This policy position is based on the lack of level 1 evidence (randomized trial and/or meta-analyses) showing superior outcomes with Inrebic (fedratinib) over Jakafi (ruxolitinib) in the first line setting for the above-mentioned indications. Please refer to UM ONC_1242 Jakafi (ruxolitinib) policy.~~	NCH PDL
UM ONC_1381	Padcev (enfortumab vedotin-ejfv)	Positive change	Add inclusion criteria: B.Urothelial Cancer 1.The member has locally advanced or metastatic urothelial carcinoma and Padcev (enfortumab vedotin-ejfv) is being used as a single agent in members who: a.Have previously received Check Point Inhibitor therapy (~~PD-1 or PD-L1 inhibitorse~~.g., pembrolizumab, avelumab, atezolizumab, nivolumab) and a platinum (cisplatin/carboplatin) containing chemotherapy regimen in the neoadjuvant/adjuvant, locally advanced, or metastatic setting, OR b.Have previously received Immune Checkpoint Inhibitor therapy (e.g., pembrolizumab, atezolizumab, nivolumab) and are ineligible for platinum-based therapy.	FDA labeling
UM ONC_1381	Padcev (enfortumab vedotin-ejfv)	Negative change	Add exclusion criteria: A.Padcev (enfortumab vedotin-ejfv) is being used after disease progression with ~~the same~~ enfortumab containing regimen.	FDA labeling

UM ONC_1382	Soliris (eculizumab)	Positive change	Remove inclusion criteria: C.Atypical Hemolytic Uremic Syndrome (aHUS) 1.The member has aHUS and Soliris (eculizumab) is being for a confirmed diagnosis of atypical HUS with evidence of hemolysis (LDH above normal/Haptoglobin below normal/Schistocytes on peripheral smear) and impaired renal function (serum creatinine above normal). ~~Unless contraindications or intolerance exist, the member has had failure to/contraindication to prior treatment with Ultomiris (ravulizumab). This recommendation is based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) to support that Soliris (eculizumab) is superior to Ultomiris (ravulizumab). Please refer to UM ONC_1386 Ultomiris (ravulizumab) policy.~~	NCH PDL
UM ONC_1385	Tazverik (tazemetostat)	Positive change	Add inclusion criteria: C.Follicular Lymphoma ~~1.Tazverik (tazemetostat) may be used for Follicular Lymphomaas follows:~~ ~~a.The member has relapsed or refractory follicular lymphoma positive for EZH2 mutation, as detected by an FDA-approved test (e.g., the cobas EZH2 Mutation Test), and the member has experienced disease progression on 2 prior lines of therapy (e.g., single agent rituximab, bendamustine + rituximab).~~ 1.Tazverik (tazemetostat) may be used as monotherapy for relapsed or refractory Follicular Lymphoma, as subsequent therapy, regardless of EZH2 mutation status.	FDA labeling
UM ONC_1385	Tazverik (tazemetostat)	Positive change	Remove exclusion criteria: ~~B.Lack of documentation of a positive EZH2 mutation (applies to follicular lymphoma only).~~	FDA labeling
UM ONC_1386	Ultomiris (ravulizumab)	No Clinical Changes	N/A	N/A
UM ONC_1403	Elitek (rasburicase)	No Clinical Changes	N/A	N/A
UM ONC_1404	Qinlock (ripretinib)	Positive change	Remove inclusion criteria: B.Gastrointestinal Stromal Tumor (GIST) 1.Qinlock (ripretinib) may be used as a single agent, for members with advanced/metastatic/inoperable GIST (Gastrointestinal Stromal Tumor) and have experienced disease progression and/or have contraindications, or intolerance to 3 lines of therapy including Gleevec (imatinib), Sutent (sunitinib), and Stivarga (regorafenib). ~~The above position is based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) to support superior outcomes with Qinlock (ripretinib) over any of the other 3 agents listed above.~~	FDA labeling
UM ONC_1408	Zepzelca (lurbinectedin)	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1411	Blenrep (belantamab mafodotin-blmf)	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1420	Margenza (margetuximab-cmkb)	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1424	Cosela (trilaciclib)	No Clinical Changes	NCH VBI language change	NCH VBP
UM ONC_1439	Empaveli (pegcetacoplan)	No Clinical Changes	N/A	N/A
UM ONC_1441	Rybrevant (amivantamab-vmjw)	No Clinical Changes	N/A	N/A
UM ONC_1464	Pyrukynd (mitapivat)	Negative change	Add exclusion criteria: E.Treatment with Pyrukynd (mitapivat) exceeds the maximum limit of 60 (5 mg), ~~30~~ 60 (20mg), ~~30~~ 60 (50 mg) tablets/month	FDA labeling

Reasons for Changes	Descriptions
NCH VBP	NCH value base program (VBP) serves as a tool to improve health outcomes and quality of cancer care by promoting utilization of NCH L1 pathways and discouraging utilization of low value regimens. NCH L1 pathways and Low Value Regimens are evaluated on the strength of evidence (efficacy, toxicity, and cost) and are approved by NCH Policy Committees and the Oncology Scientific Advisory Board.
NCH PDL	NCH Preferred Drug List (PDL) is a list of medications/regimens within the same pharmacologic class that NCH identified as having equal or higher levels of evidence supporting their effectiveness, least toxicity, and all factors being equal, lowest cost. NCH PDL serves as a tool for appropriate drug utilization and guidance to the preferred alternative drugs or regimens.
New FDA Drug/Indication	A new FDA drug or indication is a newly developed drug entity or label expansion of an existing FDA marketed drug approved by the FDA. The new to market drug/indication is published on the FDA website and CMS approved compendia.
FDA labeling	Drug criteria are from the FDA label prescribing information.
Compendia Listing	Drug criteria are from CMS approved compendia: Elsevier Clinical Pharmacology, Micromedex, NCCN Drugs & Biologics Compendium, and/or AHFS Drug Information or Wolters Kluwer Lexi-Drugs.
Clinical Trial Analysis/Criteria	Drug criteria are supported by clinical research published in peer reviewed medical journals and/or pivotal clinical trials.
FDA/NCCN/Manufacturer Withdrawal	The withdrawal of a drug/indication voluntarily by the manufacturer, NCCN, or FDA for lack of support from confirmatory data following accelerated approval, lack of clinically meaningful outcomes, and/or an increase in severe toxicities that outweighs the benefits.
Archive policy	A policy is archived when a drug is withdrawn from the market or when a drug becomes available in a generic formulation, which is preferred over the brand name product.
N/A	Not applicable is used when there are no clinical changes to an existing policy or for a newly developed drug policy.
Other	Besides those mentioned above, other clinical rationales may also be used and will be defined here.