Policy	Drug(s)	Type of Change	Brief Description of Policy Change
UM ONC_1038	Emend (Aprepitant oral or Fosaprepitant), Cinvanti (aprepitant injection) and Varubi (rolapitant oral/injection)	Negative change	Add inclusion criteria: a.Note: Per NCH policy, intravenous Emend (fosaprepitant) is preferred over oral Emend (aprepitant).
UM ONC_1038	Emend (Aprepitant oral or Fosaprepitant), Cinvanti (aprepitant injection) and Varubi (rolapitant oral/injection)	Positive change	Remove exclusion criteria: - Varubi (rolapitant oral/injection) is being used in patients with severe hepatic impairment (Child-Pugh class C) or with CYP2D6 substrates with a narrow therapeutic index such as thioridazine and pimozide. - Emend or Cinvanti is being used concomitantly with pimozide, thioridiazine, terfenadine, astemizole, or cisapride.
UM ONC_1042	Somatostatin Analog: Sandostatin (octreotide) and Somatuline (lanreotide)	Negative change	Add inclusion criteria: 3.NETS: Neuro Endocrine - a.Somatostatin Analog is being used in member with metastatic/unresectable neuroendocrine tumors originating in the gastrointestinal tract/pancreas/lung/adrenal glands/other organs (except small cell lung cancer) as a single or in combination with other therapies. 4.Thymomas and Thymic Carcinomas a.The member has unresectable/metastatic thymomas or thymic carcinomas AND b.The tumor/disease is positive on an Octreoscan (or similar imaging confirming that the tumor is somatostatin receptor positive)
UM ONC_1042	Somatostatin Analog: Sandostatin (octreotide) and Somatuline (lanreotide)	Positive change	Remove inclusion criteria: 4.Thymomas and Thymic Carcinomas Sandostatin SQ or LAR depot (octreotide) is being used ~~as second line therapy~~ for locally advanced/metastatic disease with or without prednisone
UM ONC_1042	Somatostatin Analog: Sandostatin (octreotide) and Somatuline (lanreotide)	Positive change	Remove exclusion criteria: 1.Dosing exceeds single dose limit from 40 to 60 mg Sandostatin LAR depot
UM ONC_1072	Myeloid Growth Factors	Positive change	Add inclusion critiera: 3.MGF use is supported as Secondary Prophylaxis for members with solid tumors or non-myeloid malignancies who experienced any of the following: a.A prior episode of febrile neutropenia with the current chemotherapy OR b.A neutropenic event leading to chemotherapy dose delay or dose decrease in the curative intent setting. E.Use of MGF in members receiving concurrent chemoradiation 1.For members on concurrent chemoradiation, the use of long acting MGF (e.g. pegfilgrastim and biosimilars) is not recommended per NCH policy. 2.For members on concurrent chemoradiation, the use of short acting MGF (e.g. filgrastim and biosimilars) will be reviewed on a case by case basis.
UM ONC_1133	Erbitux (Cetuximab)	Negative change	Add inclusion criteria: 2.Head and Neck Cancers a.Note: Randomized data have shown that Erbitux (cetuximab) + radiation therapy is inferior to cisplatin + radiation therapy. Therefore, the use of Erbitux (cetuximab) + radiation therapy for curative intent is only recommended for members who have a contraindication to cisplatin use. 3.Colorectal Cancer a.The member has stage IV, KRAS/NRAS Wild-Type metastatic colorectal cancer and Erbitux (cetuximab) is being used as a single agent or in combination with FOLFIRI, or FOLFOX, or irinotecan in the initial or subsequent line setting, except for members who have experienced disease progression on prior therapy with Erbitux(cetuximab) or Vectibix (panitumumab)
UM ONC_1133	Erbitux (Cetuximab)	Positive change	Remove inclusion criteria: 2.Head and Neck Cancers ii.Sequential chemoradiation (Erbitux + Radiation) following induction chemotherapy 3.Colorectal Cancer i.Initial therapy: A.In combination with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or FOLFIRI (fluorouracil, leucovorin, and irinotecan) regimen OR B.As a single agent. ii.Recurrent therapy [not previously treated with Erbitux (cetuximab) or Vectibix (panitumumab)] A.For disease previously treated with oxaliplatin based chemotherapy without irinotecan (i.e. FOLFOX OR CAPEOX/XELOX): used in combination with FOLFIRI (fluorouracil, leucovorin, and irinotecan), irinotecan. or as a single agent OR B.For disease previously treated with irinotecan- based chemotherapy without oxaliplatin (i.e. FOLFIRI): used in combination with irinotecan, FOLFOX (fluorouracil, leucovorin, and oxaliplatin) regimen, or as
UM ONC_1133	Erbitux (Cetuximab)	Positive change	Remove exclusion criteria Off-label indications for Erbitux (cetuximab) in NSCLC.

UM ONC_1192	Afinitor (everolimus)	Positive change	Remove inclusion criteria: 3.Renal Cell Carcinoma (RCC) a.Subsequent therapy as a single agent OR in combination with Lenvima lenvatinib(lenvatinib) or /Avastin (bevacizumab) for relapsed or medically unresectable stage IV disease in members who have progressed on prior tyrosine kinase inhibitor, including Sutent (sunitinib), Nexavar (sorafenib), or Votrient (pazopanib) therapy. 5.Lung Neuroendocrine tumor a.Used as treatment for stage IIIb-IV or unresectable low- or intermediate-grade neuroendocrine carcinoma. 6.Waldenström's macroglobulinemia/Lymphoplasmacytic lymphoma a.Single-agent salvage therapy for disease that does not respond to primary therapy or for progressive or relapsed disease. 7.Hodgkin Lymphoma a.Used subsequent therapy as a single agent for refractory or relapsed disease. 9.Soft Tissue Sarcoma – PEComa/Recurrent Angiomyolipoma/Lymphangioleiomyomatosis a.Used in combination with either Gleevec (imatinib), Sutent (sunitinib), or Stivarga (regorafenib) for disease progression after single-agent therapy with Gleevec (imatinib), Sutent (sunitinib), and Stivarga (regorafenib). 10.Thymomas and Thymic Carcinomas
UM ONC_1192	Afinitor (everolimus)	Positive change	Remove exclusion criteria: 1.The member has stage I-III RCC OR has not progressed on a TKI, including Nexavar (sorafenib), Sutent (sunitinib), or Votrient (pazopanib). 2.The member has neuroendocrine pancreatic tumor which is resectable.
UM ONC_1201	Yervoy (ipilimumab)	Negative change	Remove inclusion criteria: 4.Small Cell Lung Cancer a.The member has SCLC and Yervoy (ipilimumab) will be used in combination with Opdivo (nivolumab) as subsequent therapy and the member has not experienced disease progression on other PD-1/PDL-
UM ONC_1205	Halaven (eribulin)	Positive change	Add inclusion critiera: 2.Breast Cancer a.The member has recurrent or metastatic breast cancer, and Halaven (eribulin) is being used a s a single agent
UM ONC_1205	Halaven (eribulin)	Negative change	Add inclusion criteria: 3.Soft Tissue Sarcoma Members with metastatic/unresectable liposarcoma with disease progression on anthracycline based therapy and A randomized phase III trial showed improved OS in metastatic liposarcoma compared to dacarbazine. There was no benefit in leiomyosarcoma and other sarcoma subtypes were not studied. for palliative therapy in the member with disease progression on an anthracycline-containing regimen.
UM ONC_1205	Halaven (eribulin)	Positive change	Remove inclusion criteria: 2.Breast Cancer c.The member has failed both an anthracycline and a taxane in either the metastatic or adjuvant setting.
UM ONC_1205	Halaven (eribulin)	Positive change	Remove exclusion criteria: 1.The member did not receive prior treatment with an anthracycline AND taxane based chemotherapy for breast cancer or prior anthracycline containing regimen for liposarcomasoft tissue sarcoma.
UM ONC_1206	Xalkori (crizotinib)	Negative change	Add inclusion criteria: NSCLC NOTE#2: For ROS1 + metastatic Non Small Cell Lung Cancer, crizotinib is the preferred agent for patients without brain metastases, and Entrectinib is preferred for patients with brain metastases because of improved brain penetration i.ROS1 rearrangement-positive tumors without brain metastases as first line or subsequent therapy OR
UM ONC_1220	Arzerra (ofatumumab)	Positive change	Remove Inclusion criteria: 2. CLL a. The member has CLL which in the clinician's judgment requires therapy AND Arzerra (ofatumumab) is being used for the following: i. In combination with bendamustine as first line therapy OR ii. As a single agent or in combination with FC (fludarabine, cyclophosphamide) for members with relapsed or refractory disease OR iii. Maintenance therapy as second-line extended dosing following complete or partial response to treatment for relapsed or refractory disease. 3.Waldenstrom's Macroglobulemia a.The member has Waldenström Macroglobulinemia and Arzerra (ofatumumab) is being as a single agent or combination therapy for Rituximab – intolerant members who don't respond to primary therapy.
UM ONC_1220	Arzerra (ofatumumab)	Negative change	Add inclusion criteria: 2.Chronic Lymphocytic Leukemia (CLL) NOTE: Per NCH Policy and NCH Pathways, Arzerra (ofatumumab) is not recommended for use in CLL. Several alternative/superior options are available. Please refer to the NCH Pathway document for details.
UM ONC_1245	Xofigo (radium Ra 223 dichloride)	Positive change	Add inclusion critiera: 2.Prostate Cancer NOTE: Xofigo is a non-preferred drug per NCH Policy & NCH Pathways. Xofigo may be used in members with metastatic castrate-resistant prostate cancer who have symptomatic bone metastases (e.g. bone pain) and do not have visceral metastases a.Xofigo must not be combined with abiraterone as detrimental outcomes have been noted in studies
UM ONC_1245	Xofigo (radium Ra 223 dichloride)	Positive change	Remove inclusion criteria: The member has hormone refractory disease and bone metastases AND The member has symptomatic disease (i.e. cancer related bone pain on analgesic medication or treatment with external beam radiation therapy for bone pain) AND The member has no known visceral
UM ONC_1245	Xofigo (radium Ra 223 dichloride)	Negative change	Add exclusion criteria: 2.Use with Zytiga (abiraterone) is contraindicated with Xofigo (radium Ra 223 dichloride).
UM ONC_1245	Xofigo (radium Ra 223 dichloride)	Positive change	Remove exclusion criteria: 3.The presence of visceral metastatic disease ~~or malignant lymphadenopathy.~~
UM ONC_1248	Ixempra(ixabepilone)	Positive change	Remove exclusion criteria: 3.AST or ALT greater than 2.5 times the upper limit of normal (ULN) or bilirubin greater than one times ULN due to increased risk of toxicity and neutropenia-related death.

UM ONC_1249	Mekinist (trametinib)	Negative change	Add inclusion critiera: 2. Malignant Melanoma NOTE #1: The preferred combination for targeted therapy of metastatic/unresectable/recurrent BRAF V600E malignant melanoma, per NCH Policy & NCH Pathway is [vemurafenib + cobimetinib] NOTE#2: Mekinist (trametinib) may be used in combination with dabrafenib, as first line, second-line, or subsequent treatment for metastatic or unresectable disease, if member is intolerant to/has a contraindication to the preferred combination [Vemurafenib+ Cobimetinib] NOTE# 3: Mekinist(trametinib) + dabrafenib may be used an a member with The member has BRAF V600E mutation positive malignant melanoma as adjuvant treatment after complete resection of the
UM ONC_1249	Mekinist (trametinib)	Negative change	Remove inclusion criteria: Melanoma Mekinist (trametinib) is being used in combination with Tafinlar (dabrafenib) as any of the following: i.As adjuvant treatment after complete resection of the primary lesion and completion of a regional lymph node dissection OR ii.As initial treatment for recurrent/metastatic disease, including satellite/in-transit recurrence or metastases OR iii.As first line, second-line, or subsequent treatment for metastatic or unresectable disease, if targeted therapy not previously used. 5.Colorectal Cancer a.The member has unresectable, advanced, or metastatic BRAF V600E mutation positive colorectal cancer and Mekinist (trametinib) is being used in combination with dabrafenib and cetuximab/panitumumab as any of the following: i.Primary treatment OR ii.Subsequent therapy if targeted therapy not previously used. 6.Ovarian Cancer a.Mekinist (trametinib) is being used as recurrent therapy for low grade serous carcinoma.
UM ONC_1249	Mekinist (trametinib)	Positive change	Remove exclusion criteria: 1.The member has BRAF wild-type melanoma, NSCLC, or anaplastic thyroid cancer, ~~or colorectal cancer.~~ 3.Previous treatment with BRAF or MEK inhibitor (i.e. vemurafenib, dabrafenib, cobimetinib, binimetinib, or trametinib).
UM ONC_1249	Mekinist (trametinib)	Negative change	Add exclusion criteria: 2.Disease progression while taking taking any MEK inhibitors + BRAF inhibitor combination.
UM ONC_1265	Zykadia (ceritinib)	Negative change	Add inclusion criteria: Zykadia (ceritinib) may be used for first line therapy of ALK+ metastatic NSCLC if the member is intolerant /has a contraindication to Alcensa (alectinib). Zykadia (ceritinib) may be used for second line or subsequent therapy for ALK+ metastatic NSCLC if the member has experienced disease progression on Alcensa (alectinib), or Xallakori (crizotinib).
UM ONC_1265	Zykadia (ceritinib)	Positive change	Remove inclusion criteria: NSCLC The member has locally advanced, recurrent, or metastatic NSCLC and Zykadia (ceritinib) is being used as a single agent for ALL of the following conditions: i.The member has anaplastic lymphoma kinase (ALK)-positive NSCLC AND ii.Zykadia (ceritinib) is being used for subsequent therapy following disease progression on first-line therapy with another ALK inhibitor, e.g. Alcensa (alectinib) or Xalkori (crizotinib).
UM ONC_1274	Opdivo (nivolumab)	Negative change	Remove inclusion criteria: I.Small Cell Lung Cancer (SCLC) 1.The member has recurrent/relapsed SCLC and Opdivo (nivolumab) is being used as a single agent o ~~r in combination with Yervoy (ipilimumab)~~ as subsequent therapy beyond second line AND
UM ONC_1276	Onivyde (irinotecan liposome injection)	Negative change	Add inclusion criteria: 2.Metastatic adenocarcinoma of the pancreas NOTE: Onyvide (liposomal irinotecan) is a non-preferred drug per NCH Policy and NCH Pathways Onyvide (liposomal irinotecan) may be used for members with metastatic pancreas cancer who have progressed on prior therapy with both a gemcitabine-based regimen (e.g. gemcitabine + nab-paclitaxel) and FOLFIRINOX(except when patient was felt to be unfit for this regimen). 2.Onyvide must be used with 5 Fu and leucovorin
UM ONC_1276	Onivyde (irinotecan liposome injection)	Positive change	Remove inclusion criteria: a.Onivyde (irinotecan liposome) must be used in combination with fluorouracil and leucovorin AND b.Member must have progressed on prior treatment of a fluoropyrimidine or gemcitabine-based therapy AND c.Member must NOT have failed prior therapy with irinotecan HCL (non-liposomal formulation).
UM ONC_1276	Onivyde (irinotecan liposome injection)	Positive change	Remove exclusion criteria: 2.Disease progression while taking irinotecan HCL (non-liposomal formulation).
UM ONC_1277	Alecensa (Alectinib)	Positive change	Remove inclusion criteria: NSCLC iii.As subsequent therapy ~~following disease progression on first-line therapy~~ OR iv.Continuation of therapy if used first line.
UM ONC_1282	Imlygic (Talimogene Laherparepvec)	Negative change	Add inclusion criteria: 2.Melanoma NOTE#1: Imlygic is indicated ONLY for use as intra-lesional injections for visible/metastatic malignant melanoma skin lesions NOTE#2: Imlygic is not recommended per NCH Policy or NCH Pathway for combination therapy with Checkpoint Inhibitors, e.g. ipilimumab, nivolumab, and pembrolizumab. There are no randomized trials supporting the superiority of Checkpoint Inhibitors + Imlygic over either therapy given alone. i.The member has stage IIIB, IIIC, or IV melanoma and Imylgic is being used as a single agent as an intra-lesional injection for unresectable, in-transit/distant/locally recurrent skin metastases from
UM ONC_1282	Imlygic (Talimogene Laherparepvec)	Positive change	Remove inclusion criteria: In melanoma for: i.Unresectable stage III in-transit metastases ii.Local/satellite and/or in-transit unresectable recurrence iii.Unresectable or distant metastatic disease.
UM ONC_1282	Imlygic (Talimogene Laherparepvec)	Positive change	Remove exclusion criteria: 3.Member is immunocompromised or has any immune-mediated events. 4.Member has a Herpetic infection and on anti-herpetic treatment.

UM ONC_1284	Ninlaro (ixazomib)	Negative change	Add inclusion criteria: 2.Multiple Myeloma NOTE#1: Ninlaro (ixazomib) containing regimens are Non-Preferred regimens per NCH Policy and NCH Pathway for both initial therapy and for relapsed/refractory multiple myeloma NOTE#2: Ninlaro(ixazomib) is Non-Preferred for any maintenance therapy, including maintenance after HSCT
UM ONC_1284	Ninlaro (ixazomib)	Negative change	Remove inclusion criteria: i.Primary chemotherapy or for disease relapse after 6 months following primary chemotherapy with the same regimen: 1.In combination with lenalidomide and dexamethasone OR 2.In combination with cyclophosphamide and dexamethasone for transplant candidates OR ii.Maintenance: as a single agent for transplant candidates. iii.Relapse, progressive, or refractory disease 3.In combination with dexamethasone and pomalidomide ~~for members who have received at least two prior therapies including an immunomodulatory agent and a proteasome inhibitor and who have demonstrated disease progression on or within 60 days of completion of the last therapy.~~
UM ONC_1284	Ninlaro (ixazomib)	Positive change	Remove exclusion criteria: 1.History of refractory disease on Ninlaro (ixazomib), proteasome inhibitor (i.e. bortezomib or carfilzomib), or immunodulatory agent (i.e. lenalidomide or pomalidomide). Refractory disease is defined as disease progression on treatment or progression within 60 days after the last dose of a given therapy. 2.Members have not received/experienced disease progression on regimens containing all of the following: bortezomib, lenalidomide and daratumumab (all 3 drugs don't have to be present in the same
UM ONC_1287	Tagrisso (osimertinib)	Negative change	Add inclusion criteria: 2.Non-Small Cell Lung Cancer (NSCLC) Per NCH Policy & NCH Pathways Tagrisso(osimertinib) is the PREFERRED Drug in the following clinical scenarios for: a First line therapy of recurrent/metastatic, EGFR mutation positive Non-Small Cell Lung Cancer. Rationale: FLAURA trial including long term follow up of this trial b.The member has recurrent or metastatic, EGFR + (Exon 19 deletion or Exon 21 L858R point mutation) c.The member has EGFR + (Exon 19 deletion or Exon 21 L858R point mutation), stage II-IIIA, Non Small Cell Lung Cancer, that has been surgically 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.
UM ONC_1287	Tagrisso (osimertinib)	Negative change	Add exclusion criteria: 1.Concurrent use with cytotoxic chemotherapy. Prior adjuvant chemotherapy for stage II-IIIA resected, EGFR+ NSCLC is allowed. 3.Member has an uncommon EGFR mutation, especially and Exon 20 mutation
UM ONC_1287	Tagrisso (osimertinib)	Positive change	Remove exclusion criteria: 1.Symptomatic congestive heart failure or life-threatening arrhythmias. 2.Interstitial lung disease/pneumonitis, that is caused by or is related to Tagrisso therapy
UM ONC_1288	Fusilev (levoleucovorin)	Positive change	Remove inclusion critiera: a.The member has ~~advanced c~~olorectal cancer and Fusilev/Khapzory ~~(if there are contraindications/intolerance/failure to Fusilev)~~ is being used only when Leucovorin is not available at the office and the shortage is reported on FDA drug shortage website1 AND b.Fusilev/Khapzory ~~(if there are contraindications/intolerance/failure to Fusilev)~~ is being used in combination with fluorouracil-based regimens in ONE of the following conditions: i.For potentiation of fluorouracil therapy in the treatment of colorectal cancer
UM ONC_1290	Yondelis (trabectedin)	Positive change	Add inclusion critiera: 2.Soft Tissue Sarcoma a.The member has unresectable or metastatic soft tissue sarcoma (Leiomyosarcoma, liposarcoma, and translocation-related sarcomas) b.Yondelis (trabectedin) is being used as a single agent ~~palliative therapy~~
UM ONC_1290	Yondelis (trabectedin)	Negative change	Add exclusion criteria: 2.Yondelis use in sarcomas other than leiomyosarcoma, liposarcoma and translocation-associated sarcomas. 3.[In the phase III TSAR trial, patients with non-liposarcoma/LMS histotypes, trabectedin had no objective tumor responses relative to the liposarcoma/LMS group (0 versus 19 percent) and had similar PFS to those receiving best supportive care (median 1.8 versus 1.5 months). In contrast, for those with liposarcoma/LMS, trabectedin demonstrated improved PFS relative to best supportive care (median 5.1
UM ONC_1290	Yondelis (trabectedin)	Positive change	Remove exclusion criteria: 4.Significant chronic liver disease, such as cirrhosis or active hepatitis requiring antiviral therapy.
UM ONC_1377	Brukinsa (zanubrutinib)	Negative change	Add inclusion criteria: f.Mantle Cell Lymphoma i.Note: Per NCH L1 pathway and NCH policies, Imbruvica (ibrutinib) is the preferred Bruton's tyrosine kinase (BTK) inhibitor over Brukinsa (zanubrutinib).
UM ONC_1377	Brukinsa (zanubrutinib)	Positive change	Remove inclusion criteria: ii.Member is intolerant to or has a contraindication to Ibrutinib- the preferred BTK inhibitor per NCH Pathway and Policies
UM ONC_1377	Brukinsa (zanubrutinib)	Positive change	Remove exclusion criteria: 2.Clinically significant active cardiovascular disease. 3.Uncontrolled systemic infection or infection requiring anti-microbial therapy.
UM ONC_1396	Koselugo (selumetinib)	Negative change	Add inclusion criteria: 2.Plexiform Neurofibromas (PN) ii.Positive genetic testing for neurofibromatosis type 1 (NF1) mutation