Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
New	Pyrukynd (mitapivat)	N/A	N/A	N/A
UM ONC_1028	Bevacizumab Products: Avastin (bevacizumab)/Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr)/Alymsys (bevacizumab-maly)	Positive change	Add inclusion criteria: Add new biosimilar, Alymsys™ (bevacizumab-maly)	Per FDA labeling
UM ONC_1028	Bevacizumab Products: Avastin (bevacizumab)/Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr)/Alymsys (bevacizumab-maly)	Positive change	Add inclusion criteria: D.Non-Small Cell Lung Cancer (NSCLC) 1.The member has recurrent, advanced, or metastatic non-squamous non-small cell lung cancer and Bevacizumab/bevacizumab biosimilar will be used as first line therapy in combination with carboplatin and paclitaxel.	Per FDA labeling
UM ONC_1028	Bevacizumab Products: Avastin (bevacizumab)/Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr)/Alymsys (bevacizumab-maly)	Negative change	Add inclusion criteria: For all indications, where applicable: 3.NOTE: Per NCH Pathway & NCH Policy, Avastin (bevacizumab) is a non-Preferred drug. Mvasi (bevacizumab-awwb) and Zirabev (bevacizumab-bvzr) are the Preferred products whenever Bevacizumab is requested. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes for one Bevacizumab product over another.	Per NCH Pathway exclusion
UM ONC_1035	5HT3 Receptor Antagonists	Positive change	Add inclusion criteria: 2.Zofran (ondansetron), OR Kytril (Granisetron), or Aloxi (palonosetron) may be used prior to the administration of low, moderate, or highly emetogenic chemotherapy.	More Cost Effective Alternative(s)
UM ONC_1035	5HT3 Receptor Antagonists	Negative change	Remove inclusion criteria: 3.Aloxi (palonosetron) is being used in any of the following situations: a.Before moderately/highly emetogenic chemotherapy (emetogenicity of agent/regimen is based on the antiemetic practice guideline from NCCN) OR b.Before low or minimal emetic risk chemotherapy in members who failed or are intolerant to or have a contraindication to Zofran (ondansetron) or Granisetron. 4.Akynzeo (netupitant oral/fosnetupitant injection-palonosetron) is being used before moderate/highly emetic risk chemotherapy. 5.Sancuso (granisetron PATCH) is being used before moderate/highly emetogenic risk chemotherapy.	More Cost Effective Alternative(s)
UM ONC_1035	5HT3 Receptor Antagonists	Positive change	Add inclusion criteria: 3.Sustol (granisetron extended release), Akynzeo (netupitant oral/fosnetupitant injection + palonosetron), or Sancuso (granisetron PATCH) is being used as ONE of the following: a.Before or after highly emetogenic chemotherapy, for example cisplatin or anthracycline and cyclophosphamide combination chemotherapy regimens OR b.Before moderate/highly emetic risk chemotherapy in members who have failed or are intolerant to any 5HT3+ agent PLUS (fosaprepitant ~~or aprepitant~~) combination.	More Cost Effective Alternative(s)
UM ONC_1035	5HT3 Receptor Antagonists	Positive change	Remove exclusion criteria: A.Sustol is being used without failure, intolerance, or contraindications to any 5HT3 + Emend (fosaprepitant/aprepitant) combination.	More Cost Effective Alternative(s)
UM ONC_1035	5HT3 Receptor Antagonists	Negative change	Add exclusion criteria: B.A.Aloxi and Akynzeo are being used for prevention of radiation induced nausea and vomiting or for the treatment of breakthrough nausea/vomiting.	Per FDA labeling
UM ONC_1069	Trisenox (Arsenic Trioxide)	Positive change	Add inclusion criteria: B.Acute Promyelocytic Leukemia (APL) 1.Trisenox (arsenic trioxide) may be used for the treatment of members with Acute Promyelocytic Leukemia (APL)-regardless of the APL Risk Category-as induction and/or consolidation therapy for newly diagnosed or relapsed/refractory APL , either as a single agent OR in combination with one or more of the following agents: ATRA (all-trans-retinoic-acid), Gemtuzumab Ozogamicin, and an anthracycline (daunorubicin or idarubicin) .	Per FDA labeling
UM ONC_1069	Trisenox (Arsenic Trioxide)	Negative change	Add exclusion criteria: A.Disease progression on or after Trisenox (arsenic trioxide).	Per FDA labeling
UM ONC_1070	Valstar (Valrubicin)	Positive change	Add inclusion criteria: on-Muscle Invasive Bladder Cancer (Tis-Carcinoma In Situ) 1.The member has recurrent or persistent non-muscle invasive carcinoma of the bladder-Tis or Carcinoma In Situ-that is refractory /intolerant to local (intravesical) therapy with BCG. Refractory is defined as a loss of response to treatment within 6 months of induction or 12 months of maintenance with at least the first course of induction (5-6 doses) followed by maintenance/second induction (of at least 2 doses) of BCG treatment.	Per FDA labeling
UM ONC_1070	Valstar (Valrubicin)	Negative change	Add exclusion criteria: C.Total induction doses of Valstar (valrubicin) exceed 2 cycles (or 12 doses). D.Total maintenance doses of Valstar (valrubicin) exceed 10 cycles (or 10 doses).	Per FDA labeling
UM ONC_1072	Myeloid Growth Factors (Neupogen, Granix, Leukine, Zarxio, Releuko, Neulasta/Fulphila)	Positive change	Add inclusion criteria: Add new biosimilar, Releuko (filgrastim-ayow)	Per FDA labeling
UM ONC_1072	Myeloid Growth Factors (Neupogen, Granix, Leukine, Zarxio, Releuko, Neulasta/Fulphila)	Positive change	Add inclusion criteria: For all indications, where applicable: NOTE: Per NCH Pathway & NCH Policy, Zarxio (filgrastim-sndz), Granix (tbo-filgrastim), and Nivestym (filgrastim-aafi) are the Preferred medications over another short acting myeloid growth factor (MGF) such as Neupogen (filgrastim), Sargramostim (leukine), Nivestym (filgrastim-aafi), or Releuko (filgrastim-ayow). This recommendation is based on a lack of evidence (randomized clinical trial and/or meta-analyses) to show superior clinical outcomes with one MGF over another.	More Cost Effective Alternative(s)
UM ONC_1072	Myeloid Growth Factors (Neupogen, Granix, Leukine, Zarxio, Releuko, Neulasta/Fulphila)	Negative change	Add inclusion criteria: B.Prophylaxis/Prevention of Febrile Neutropenia from Chemotherapy. 3.NOTE 1: NCH Policy does not recommend the use of MGF (either short acting or long acting) for the treatment of afebrile neutropenia. This position is supported by Level 1 evidence showing no clinical benefit from MGF therapy in the above clinical setting.A Please see attachment C for MGF indications for febrile neutropenia primary and secondary prophylaxis. 4.NOTE 2: Per NCH Pathway & NCH Policy, Long Acting MGFs (pegfilgrastim products) are non-Preferred and will be approved only if there is documented confirmation of a contraindication/intolerance to a short acting MGF, member is unable to self-administer due to limitations, and the member is unable to travel to the office for daily injections. When a Short Acting MGF is indicated, Zarxio (filgrastim-sndz), Granix (tbo-filgrastim), and Nivestym (filgrastim-aafi) are the Preferred medications over another Short Acting myeloid growth factor (MGF) such as Neupogen (filgrastim), Sargramostim (leukine), Nivestym (filgrastim-aafi), or Releuko (filgrastim-ayow). This recommendation is based on a lack of evidence (randomized clinical trial and/or meta-analyses) to show superior clinical outcomes with one MGF over another. E.Use of MGF in Members Receiving Concurrent Chemoradiation 2.NOTE 1: Per NCH Pathway & NCH Policy, Zarxio (filgrastim-sndz), Granix (tbo-filgrastim), and Nivestym (filgrastim-aafi) are the Preferred medications over another short acting myeloid growth factor (MGF) such as Neupogen (filgrastim), Sargramostim (leukine), Nivestym (filgrastim-aafi), or Releuko (filgrastim-ayow), This recommendation is based on a lack of evidence (randomized clinical trial and/or meta-analyses) to show superior clinical outcomes with one MGF over another. 3.NOTE 2: For members on concurrent chemoradiation, the use of long acting MGF (e.g., pegfilgrastim and biosimilars) is not recommended per NCH policy.	More Cost Effective Alternative(s)
UM ONC_1072	Myeloid Growth Factors (Neupogen, Granix, Leukine, Zarxio, Releuko, Neulasta/Fulphila)	Positive change	Add inclusion criteria: Updates to attachments A & B tables: Low Risk Regimens (< 10% FN RISK) High Risk Regimens (< 20% FN RISK)	Per Compendia Listing

Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
UM ONC_1132	Rituxan Products (Rituxan, Rituxan Hycela, Truxima, Ruxience)	Positive change	Remove inclusion criteria: NHL/ALL 2.NOTE 1: Per NCH Pathway and NCH Policy, the following regimens are Non-Preferred due to lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes/lower toxicity compared to the NCH Preferred regimens. Please refer to NCH L1 pathway for the preferred treatments in these settings: c.As initial ~~and subsequent~~ therapy for Marginal Zone Lymphoma: lenalidomide + rituximab	Per NCH Pathway exclusion
UM ONC_1132	Rituxan Products (Rituxan, Rituxan Hycela, Truxima, Ruxience)	Negative change	Add inclusion criteria: B.CD-20 positive B-Cell Non-Hodgkin's Lymphomas (NHL) or Acute Lymphoblastic Leukemia (B-ALL) 3.NOTE 2: Per NCH Pathway & NCH Policy, Rituxan (rituximab), Rituxan Hycela (rituximab and hyaluronidase), and Riabni (rituximab-arrx) are non-Preferred drugs. Truxima (rituximab-abbs) and Ruxience (rituximab-pvvr) are the Preferred products for the treatment of CD-20 positive NHL and B-ALL. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) demonstrating superiority of one rituximab product over another. C.Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) c. NOTE 1: Per NCH Pathway and NCH Policy, the following regimens are Non-Preferred due to the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes compared to the NCH Preferred regimens. Please refer to NCH L1 pathway for the preferred treatments in these settings: i.Initial therapy: single agent rituximab, High-dose methylprednisolone (HDMP) + rituximab, ibrutinib + rituximab, fludarabine + rituximab (FR), alemtuzumab + ritixumab ii.Subsequent therapy: idelalisib + rituximab, lenalidomide + rituximab, HDMP + rituximab, dose-dense rituximab, alemtuzumab + rituximab, bendamustine + rituximab + ibrutinib. b.d. NOTE 2: Per NCH Pathway & NCH Policy, Rituxan (rituximab), Rituxan Hycela (rituximab and hyaluronidase), and Riabni (rituximab-arrx) are non-Preferred drugs. Truxima (rituximab-abbs) and Ruxience (rituximab-pvvr) are the Preferred products for the treatment of CLL/SLL. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) demonstrating superiority of one rituximab product over another. D.Hodgkin's Lymphoma 4.NOTE 2: Per NCH Pathway & NCH Policy, Rituxan (rituximab), Rituxan Hycela (rituximab and hyaluronidase), and Riabni (rituximab-arrx) are non-Preferred drugs. Truxima (rituximab-abbs) and Ruxience (rituximab-pvvr) are the Preferred products for the treatment of Hodgkin's Lymphoma. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) demonstrating superiority of one rituximab product over another. E.Idiopathic Thrombocytopenic Purpura (ITP) 4.NOTE: Per NCH Pathway & NCH Policy, Rituxan (rituximab), Rituxan Hycela (rituximab and hyaluronidase), and Riabni (rituximab-arrx) are non-Preferred drugs. Truxima (rituximab-abbs) and Ruxience (rituximab-pvvr) are the Preferred products for the treatment of ITP. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) demonstrating superiority of one rituximab product over another. F.Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma 1.2.NOTE: Per NCH Pathway & NCH Policy, Rituxan (rituximab), Rituxan Hycela (rituximab and hyaluronidase), and Riabni (rituximab-arrx) are non-Preferred drugs. Truxima (rituximab-abbs) and Ruxience (rituximab-pvvr) are the Preferred products for the treatment of Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) demonstrating superiority of one rituximab product over another.	More Cost Effective Alternative(s)
UM ONC_1134	Trastuzumab Products, Pertuzumab (pertuzumab), and Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf)	Positive change	Add inclusion criteria: 1. The member has node positive and/or tumor stage T2 or greater HER-2 positive breast cancer ANDTrastuzumab/trastuzumab biosimilar +/- Pertuzumab may be used as neoadjuvant treatment OR as adjuvant treatment in members who did not receive neoadjuvant therapy or in members who received neoadjuvant therapy and did not have any residual disease in the breast or axillary lymph nodes at surgery. The following chemotherapy regimens are acceptable for use with Trastuzumab/trastuzumab biosimilar +/- Pertuzumab combination therapy as neoadjuvant or adjuvant treatment: i.Trastuzumab /trastuzumab biosimilar +/- Pertuzumab with Paclitaxel following AC ii.Trastuzumab /trastuzumab biosimilar +/- Pertuzumab with Docetaxel following AC iii.Trastuzumab /trastuzumab biosimilar +/- Pertuzumab with Docetaxel/Paclitaxel iv.TCH (docetaxel, carboplatin, and trastuzumab /trastuzumab biosimilar) +/- Pertuzumab v.Trastuzumab /trastuzumab biosimilar with Docetaxel and Cyclophosphamide. 2.Trastuzumab /trastuzumab biosimilar +/- Pertuzumab may be use as continuation adjuvant therapy following adjuvant Trastuzumab/trastuzumab biosimilar +/- Pertuzumab + Chemotherapy. 3. Trastuzumab/trastuzumab biosimilar may be used as first line or subsequent line therapy for recurrent or metastatic HER-2 positive breast cancer: i.In combination with Novaldex (tamoxifen), Faslodex (fulvestrant), or an aromatase inhibitor for a member whose disease is also ER/PR positive OR ii.In combination with Pertuzumab and a Taxane, Taxotere (docetaxel) or Taxol (paclitaxel), regardless of the ER/PR status OR iii.In combination with other single agent chemotherapy agents e.g., vinorelbine. iii. In combination with Tukysa (tucatinib) + Xeloda (capecitabine) for members with metastatic HER2 positive breast cancer and brain metastases OR in members without brain metastases if there is disease progression on one or more prior lines of anti HER-2 therapy in the metastatic setting.	Per Compendia Listing
UM ONC_1134	Trastuzumab Products, Pertuzumab (pertuzumab), and Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf)	Positive change	Remove inclusion criteria: B.HER-2 Positive Breast Cancer 1.NOTE 1: For neoadjuvant therapy, Pertuzumab is only indicated in members with node positive and/or tumor stage T2 or greater 2.NOTE 2: For adjuvant therapy, Trastuzumab + Pertuzumab are indicated in members who did not receive neoadjuvant therapy and are node positive at surgery or who have received neoadjuvant therapy and did NOT have any residual disease in the breast and/or axillary lymph node at surgery. If there is evidence of residual disease in the breast and or axillary nodes at surgery, then the Preferred drug per NCH Policy & NCH Pathway for adjuvant therapy is Kadcyla (ado-trastuzumab). 3.NOTE 3: Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf) may be used anywhere Trastuzumab + Pertuzumab containing therapy is indicated.	Per NCH Pathway expansion
UM ONC_1134	Trastuzumab Products, Pertuzumab (pertuzumab), and Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf)	Negative change	Add inclusion criteria: 4.NOTE 1: Herceptin (trastuzumab) or Herceptin Hylecta (trastuzumab hyaluronidase) are non-Preferred drugs. Kanjinti (trastuzumab-anns), Ogivri (trastuzumab-dkst) +/- Perjeta (pertuzumab) OR Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf) are the preferred options for the treatment of HER2 positive breast cancer, This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) demonstrating superiority of one trastuzumab/trastuzumab + pertuzumab combination product over another. 5.NOTE 2: For adjuvant therapy in HER-2 positive breast cancer, Trastuzumab/trastuzumab biosimilar + Pertuzumab containing regimen is indicated in members who did not receive neoadjuvant therapy and are node positive at surgery or who have received neoadjuvant therapy and did NOT have any residual disease in the breast and/or axillary lymph node at surgery. If there is evidence of residual disease in the breast and or axillary nodes at surgery, then the Preferred drug per NCH Policy & NCH Pathway for adjuvant therapy is Kadcyla (ado-trastuzumab). This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior clinical outcomes with Trastuzumab/trastuzumab biosimilar + Pertuzumab containing regimen compared to Kadcyla (ado-trastuzumab). C.HER-2 Positive Gastric/Esophageal and Esophagogastric Junction Cancers 2.NOTE: Herceptin (trastuzumab) or Herceptin Hylecta (trastuzumab hyaluronidase) are non-Preferred drugs. Kanjinti (trastuzumab-anns) and Ogivri (trastuzumab-dkst) are the preferred options for the treatment of HER2 positive recurrent/metastatic gastric or esophageal or esophagogastric junction cancer, This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) demonstrating superiority of one trastuzumab product over another.	More Cost Effective Alternative(s)
UM ONC_1138	Erythropoiesis Stimulating Agents (ESA)	Positive change	Remove inclusion criteria: B.Chemotherapy induced anemia (CIA) a.For initial/continuation requests the baseline ~~Hgb is < 8g/dL or HCT is < 24 (as recommended by NCH L1 pathway) or~~ Hgb <10 g/dL or HCT < 30 ~~(as required by NCH policy).~~ prior to the initiation of ESA therapy (levels are obtained within the last 4 weeks)	Per Clinical Trial Analysis/Criteria

Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
UM ONC_1138	Erythropoiesis Stimulating Agents (ESA)	Negative change	Add inclusion criteria: C.Anemia of Chronic Kidney Disease (CKD) 2.ESA can be initiated and continued when Hgb < 10 g/dL or HCT < 30 (levels are obtained within the last 4 weeks). 3.NOTE: Per NCH Pathway & NCH Policy, Aranesp (darbepoetin alfa) is a non-Preferred drug. The Preferred medications are Retacrit (epoetin alfa-epbx) and Procrit/Epogen (epoetin alfa). This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with Aranesp (darbepoetin alfa) compared to Retacrit (epoetin alfa-epbx) and Procrit/Epogen (epoetin alfa). For the treatment of anemia of CKD, the member's Hgb is < 10 g/dL or HCT is < 30 within the last 4 weeks prior to start of treatment, and serum ferritin is ≥30 ng/mL AND/OR transferrin saturation is ≥ 20% within the last 12 months. D.Myelodysplastic Syndrome (MDS) 2.NOTE: Per NCH Pathway & NCH Policy, Aranesp (darbepoetin alfa) is a non-Preferred drug. The Preferred medications are Retacrit (epoetin alfa-epbx) and Procrit/Epogen (epoetin alfa). This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with Aranesp (darbepoetin alfa) compared to Retacrit (epoetin alfa-epbx) and Procrit/Epogen (epoetin alfa). For the treatment of MDS related anemia, the member's Hgb is < 10 g/dL or HCT is < 30 within the last 4 weeks prior to start of treatment, and serum ferritin is ≥30 ng/mL AND/OR transferrin saturation is ≥ 20% (levels obtained within the last 12 months) OR iron stains in the bone marrow show adequate iron.	More Cost Effective Alternative(s)
UM ONC_1138	Erythropoiesis Stimulating Agents (ESA)	Negative change	Add exclusion criteria: Investigational use of ESA with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following: a.Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence. b.Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence. c.Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definition of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of < 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months. d.Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover). e.That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs. f.That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs. g.That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.	Per Clinical Trial Analysis/Criteria
UM ONC_1193	Revlimid (lenalidomide)	Negative change	Remove inclusion criteria: 2.Revlimid (lenalidomide) is being used as a single agent or in combination with hypomethylating agent (i.e., decitabine or azacitidine) in members with MDS/Myeloproliferative Overlap Neoplasms (MPN).	Remove off label indication
UM ONC_1193	Revlimid (lenalidomide)	Positive change	Remove inclusion criteria: D.Non-Hodgkin Lymphoma (NHL) 1.The member has Non- Hodgkin's Lymphoma including Follicular Lymphoma, Nodal Marginal Zone Lymphoma, Mantle Cell Lymphoma, and Splenic Marginal Zone Lymphoma AND Revlimid (lenalidomide) may be used for relapsed/refractory disease as second-line or subsequent therapy for recurrent or progressive disease, with or without Rituxan (rituximab)/rituximab biosimilarr~~/Gazyva (obinutuzumab).~~ 2.NOTE: Per NCH Pathway & NCH Policy, the following regimens are Non-Preferred for the following treatment settings: a.Diffuse Large B Cell Lymphoma (DLBCL) maintenance: single agent Revlimid (lenalidomide). b. ~~Diffuse Large B Cell Lymphoma (DLBCL), relapsed/refractory: Lenalidomide +/- rituximab (non-GCB DLBCL).~~	Per NCH Pathway expansion
UM ONC_1199	Tasigna (nilotinib)	Positive change	Remove inclusion criteria: 3.Tasigna (nilotinib) may be used as a single agent as ANY of the following: a.Primary/initial therapy ~~in members who are intolerant or have a contraindication to Gleevec (imatinib).~~	Per NCH Pathway expansion
UM ONC_1235	Doxil or Lipodox (liposomal doxorubicin)	Negative change	Remove inclusion criteria: Remove Lipodox, product is no longer available on the market	FDA/NCCN Withdrawal
UM ONC_1258	Gilotrif (afatinib)	Positive change	Remove inclusion criteria: B.Non-Small Cell Lung Cancer (NSCLC) 1.NOTE: The preferred agent, per NCH Policy & NCH Pathway, for first line therapy of recurrent/metastatic, EGFR mutation positive Non-Small Cell Lung Cancer is Osimertinib. Please refer to UM ONC_1287 Tagrisso (osimertinib) policy. This recommendation is based on the lack of Level 1 evidence (randomized trials and or meta-analyses) to show Gilotrif (afatinib) is superior to Tagrisso (Osimertinib) for the first line treatment of EGFR mutation positive NSCLC. 1.Gilotrif (afatinib) may be used when the member has recurrent or metastatic EGFR mutation positive NSCLC and Gilotrif(afatinib) is being used as a single agent for subsequent therapy upon disease progression on another first line TKI agent (e.g., Osimertinib), and the members' cancer is negative for the T790M mutation.	Per NCH Pathway expansion
UM ONC_1258	Gilotrif (afatinib)	Positive change	Add inclusion criteria: 1.Gilotrif (afatinib) may be used as monotherapy in members with advanced/metastatic (stage IIIb or IV) NSCLC and ANY of the following: a.As first line therapy in members with EGFR positive mutation that is negative for T790M mutation or Exon 20 insertion mutation OR b.As second line/subsequent therapy following first line treatment with platinum containing chemotherapy, regardless of EGFR mutation status.	Per FDA labeling
UM ONC_1258	Gilotrif (afatinib)	Negative change	Add exclusion criteria: A.Disease progression while taking Gilotrif (afatinib). A.B.Gilotrif use in a member with advanced/metastatic Non-Small Cell Lung Cancer that is positive for the T790M mutation or EGFR Exon 20 insertion mutation.	Per FDA labeling
UM ONC_1287	Tagrisso (osimertinib)	Positive change	Remove inclusion criteria: B.None-Small Cell Lung Cancer (NSCLC) 1.Note: Per NCH Policy & NCH Pathway, Tagrisso (osimertinib) is the preferred drug in the following clinical scenarios: 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.A b.Adjuvant therapy of surgically resected, EGFR +, stages II-IIIA Non-Small Cell Lung Cancer. Rationale: ADAURA trial.	Per NCH Pathway expansion
UM ONC_1287	Tagrisso (osimertinib)	Negative change	Add exclusion criteria: A.Concurrent use with ~~cytotoxic chemotherapy~~anti-cancer therapy. Use with adjuvant chemotherapy for stage II-IIIA, completely resected, EGFR+ NSCLC is allowed. C.Member has an uncommon EGFR Exon 20 insertion mutation.	Per FDA labeling

Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
UM ONC_1313	Alunbrig (brigatinib)	Positive change	Remove inclusion criteria: B.Non-Small Cell Lung Cancer (NSCLC) 1.NOTE: The preferred targeted therapies, per NCH policy and pathway, for recurrent, advanced, or metastatic ALK+ NSCLC are as follows: a.First-line therapy: Alecensa (alectinib) b.Subsequent-line therapy: Lorbrena (lorlatinib)or Alunbrig (brigatinib). 1.For members with recurrent/metastatic Non-Small Cell Lung Cancer with a positive ALK rearrangement, Alunbrig (brigatinib) may be used as a single agent for first line or subsequent therapy ~~if there is intolerance or contraindication to Alecensa (alectinib).~~	Per NCH Pathway expansion
UM ONC_1313	Alunbrig (brigatinib)	Negative change	Add exclusion criteria: D.Treatment exceeds the maximum limit of ~~180~~ 90 (30 mg) ~~tablets/month~~ or 60 (90 mg), or 30 (180 mg) tablets/month.	Per FDA labeling
UM ONC_1315	Rydapt (midostaurin)	Negative change	Add exclusion criteria: B.Dosing exceeds single dose limit of Rydapt (midostaurin) 50 mg (for AML) or 100 mg (for ASM or SM-AHN).	Per FDA labeling
UM ONC_1329	Yescarta (axicabtagene ciloleucel)	Positive change	Remove inclusion criteria: B.Non-Hodgkin Lymphomas (NHL) 2.The member has chemotherapy-refractory disease after the following: a.Two or more lines of systemic chemotherapy OR b.For DLBCL, ~~two or~~ one or more lines of systemic chemotherapy, including rituximab and an anthracycline (e.g., R-CHOP, R-CEOP, R-EPOCH).	New FDA Indication
UM ONC_1342	Azedra (iobenguane I-131)	Positive change	Add 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.	Per FDA labeling
UM ONC_1342	Azedra (iobenguane I-131)	Negative change	Add exclusion criteria: A.Azedra (iobenguane I-131) is being used after disease progression ~~while receiving Azedra~~ on the same regimen. C.The maximum Ssingle dose limit of Azedra (iobenguane I-131) is based on weight: 1.Weight greater than 62.5 kg: 18,500 Megabecquerel (MBq) (500 Millicuries (mCi) for a total of 2 doses. 2.Weight 62.5 kg or less: 296 MBq/kg (8 mCi/kg) for a total of 2 doses.	Per FDA labeling
UM ONC_1345	Tavalisse (fostamatinib) Prev. UM_1047	Negative change	Add inclusion criteria: B.Immune Thrombocytopenic Purpura (ITP) 1.Tavalisse (fosamatinib) 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 ALL of the following criteria have been satisfied: a.The Mmember 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 30,000) to prior therapies including corticosteroids, IVIG, splenectomy/Rituxan, and/or a Thrombopoietin Receptor Agonist (romiplostim, eltrombopag or avatrombopag) AND a platelet count ≤ 30,000 prior to start of therapy OR c. ~~A platelet count ≤ 30,000 prior to start of therapy.~~ b. For continuation request: The member did not achieve a rise in Platelet counts or the member continues to experience significant bleeding any time during treatment with Tavalisse (fostamatinib).	Per Clinical Trial Analysis/Criteria
UM ONC_1345	Tavalisse (fostamatinib) Prev. UM_1047	Positive change	Remove exclusion criteria: A.Patient has not had a documented trial and failure of prior ITP therapies as described above.	Per Clinical Trial Analysis/Criteria
UM ONC_1359	Arranon (nelarabine)	Negative change	Add 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 ~~in members who have progressed after therapy with 2 or more regimens.~~ b.Therapy for Relapsed/Refractory disease in members who have progressed after therapy with 2 or more regimens ~~as a component of a nelarabine containing regimen.~~ 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.	Per NCH Pathway exclusion
UM ONC_1364	Turalio (pexidartinib)	Negative 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 is not a surgical candidate	Per FDA labeling
UM ONC_1364	Turalio (pexidartinib)	Negative change	Add exclusion criteria: A.Disease progression while receiving Turalio (pexidaritinb) or the member continued to experience no improvement in symptoms (i.e., joint pain and stiffness) on or after 3 months of treatment with Turalio (pexidartinib).	Per Clinical Trial Analysis/Criteria
UM ONC_1365	Xpovio (selinexor)	Negative change	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 ~~/Daratumumab~~ +/- Dexamethasone in members who have received one prior therapy. ~~OR in combination with Pomalyst (pomalidomide) +/- Dexamethasone following 2 prior lines of therapy including a proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib) and an immunomodulatory agent (e.g., lenalidomide, thalidomide, pomalidomide).~~	Per FDA labeling
UM ONC_1365	Xpovio (selinexor)	Negative change	Add inclusion criteria: 3.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.	Per NCH Pathway exclusion
UM ONC_1379	Enhertu (fam-trastuzumab deruxtecan-nxki)	Negative change	Remove inclusion criteria: A.HER-2 positive metastatic/recurrent Breast Cancer 1.The member has recurrent or metastatic HER2-positive breast cancer (HER-2 positivity is defined as IHC 3+ or FISH positive) AND 1.Enhertu (fam-trastuzumab deruxtecan-nxki) is being used as a single agent in a patient who has experienced disease progression on/after [Taxane (paclitaxel/docetaxel) + Herceptin (trastuzumab)/trastuzumab biosimilar + Perjeta (pertuzumab)].	Per NCH Pathway expansion

Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
UM ONC_1379	Enhertu (fam-trastuzumab deruxtecan-nxki)	Positive change	Add inclusion criteria: 1.The member has recurrent or metastatic HER2-positive breast cancer AND Enhertu (fam-trastuzumab deruxtecan-nxki) will be used as monotherapy for any of the following clinical setting: a.As first line therapy, for recurrent disease, in a member who has experienced disease progression within 6 months of neoadjuvant/adjuvant treatment or within 12 months of extended adjuvant treatment with an anti-HER2 containing regimen [e.g., Herceptin (trastuzumab)/trastuzumab biosimilar +/- Perjeta (pertuzumab) +/- chemotherapy] OR b.As second line/subsequent therapy in the metastatic setting.	New FDA Indication
UM ONC_1382	Soliris (eculizumab)	Negative change	Add exclusion criteria: A.Disease progression while on Soliris (eculizumab) defined by a lack of response in rise of hemoglobin and continued use of blood transfusions. B.Soliris (eculizumab) is being used after disease progression with the same regimen or other anti-complement therapies, for example Ultomiris (ravulizumab).	Per Clinical Trial Analysis/Criteria
UM ONC_1385	Tazverik (tazemetostat)	Positive change	Add inclusion criteria: B.Epithelioid Sarcoma 1.The member is an adult or pediatric member 16 years of age and older with ~~has relapsed/refractory~~ unresectable advanced or metastatic epithelioid sarcoma and the member is not a candidate for surgery and/or radiation and Tazverik (tazemetostat) is being used as a single agent	Per FDA labeling
UM ONC_1386	Ultomiris (ravulizumab)	Positive change	Remove inclusion criteria: C.Atypical Hemolytic Uremic Syndrome (aHUS) 1.Ultomiris (ravulizumab) is preferred over Soliris (eculizumab) for the treatment of aHUS unless there are contraindications or intolerance to Ultomiris (ravulizumab). This recommendation is based on the cost effectiveness data available with the use of a reduced dosing frequency of Ultomiris (ravulizumab) for the treatment of aHUS.	More Cost Effective Alternative(s)
UM ONC_1386	Ultomiris (ravulizumab)	Negative change	Add exclusion criteria: B.Disease progression while on Ultomiris (ravulizumab) defined by a lack of response in rise of hemoglobin and continued use of blood transfusions.	Per Clinical Trial Analysis/Criteria
UM ONC_1401	Tukysa (tucatinib)	Positive change	Remove inclusion criteria: B.Breast Carcinoma 1.NOTE: Per NCH Pathway & NCH Policy, Tukysa (tucatinib) is non-preferred in members with metastatic HER2 positive breast cancer, except in members with brain metastases. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior clinical outcomes with Tukysa (tucatinib) compared to another anti-HER2 based regimen. Please refer to NCH Pathway for the preferred treatments recommended for use in metastatic HER2 positive breast cancer. 1.Tukysa (tucatinib) may be used in members with metastatic HER2 positive breast cancer and brain metastases OR in members without brain metastases if there is disease progression. contraindication, or intolerance to ~~2~~one or more prior anti HER-2 therapies in the metastatic setting ~~including Kadcyla (ado- trastuzumab) and a a trastuzumab containing regimen~~ [e.g., Trastuzumab + Pertuzumab/Lapatinib +/- Chemotherapy]	Per NCH Pathway expansion
UM ONC_1403	Elitek (rasburicase)	Negative change	Add inclusion criteria: B.Tumor Lysis Syndrome (TLS) 1.Elitek (Rasburicase) may be used either as a single agent or in combination with allopurinol, for prevention and or treatment of TLS-Tumor Lysis Syndrome- in adult or pediatric members with hematologic malignancies/solid tumors that are receiving anti-cancer therapy and are expected to be at a significant risk of developing TLS or have clinical/laboratory evidence of TLS with an increase in plasma uric acid level above the upper limit of normal.	Per Clinical Trial Analysis/Criteria
UM ONC_1403	Elitek (rasburicase)	Negative change	Add exclusion criteria: A.Dosing exceeds single dose limit of Elitek (rasburicase) 0.15 ~~2~~ mg/kg (up to maximum ~~7.5~~ 6 mg fixed single dose). B.Treatment exceeds the maximum duration limit of 5 days which is equivalent to one course of treatment.	Per FDA labeling
UM ONC_1404	Qinlock (ripretinib)	Negative change	Add exclusion criteria: B.Concurrent use with other ~~TKIs (Tyrosine Kinase Inhibitors)~~ anti-cancer therapy.	Per Clinical Trial Analysis/Criteria
UM ONC_1406	Tabrecta (capmatinib)	Positive change	Add inclusion criteria: 2.Tabrecta (capmatinib) is being used as a single agent either as first line/initial therapy or as second/subsequent line of therapy (if not used previously as initial therapy).	Per Clinical Trial Analysis/Criteria
UM ONC_1406	Tabrecta (capmatinib)	Negative change	Add exclusion criteria: A.Disease progression while receiving Tabrecta (capmatinib) or another MET inhibitor [e.g., Tepmetko (tepotinib)].	Per Clinical Trial Analysis/Criteria
UM ONC_1434	Zynlonta (loncastuzimab tesirine-lpyl)	Positive change	Remove inclusion criteria: B.Diffuse Large B-Cell Lymphoma (DLBCL) 1.NOTE: Per NCH Policy & NCH Pathway, Zynlonta (loncastuzimab tesirine-lpyl) is non-preferred for relapsed or refractory DLBCL. This recommendation is based on a lack of level 1 evidence (clinical trial and/or meta-analysis) comparing Zynlonta (loncastuzimab tesirine-lpyl) to other available therapies.	Per NCH Pathway expansion
UM ONC_1439	Empaveli (pegcetacoplan)	Negative change	Add exclusion criteria: B.Concurrent administration with Soliris (eculizumab) beyond 4 weeks of Empaveli (pegcetacoplan) treatment. When switching from Soliris (eculizumab) to Empaveli (pegcetacoplan), a 4 week run in period is recommended to reduce the risk of hemolysis with abrupt discontinuation.	Per Clinical Trial Analysis/Criteria
UM ONC_1440	Lumakras (sotorasib)	Positive change	Add inclusion criteria: B.Non-Small Cell Lung Cancer 1.Lumakras (sotorasib) may be used as monotherapy for members with locally advanced or metastatic NSCLC, who have received prior therapy with platinum-based chemotherapy, with or without immunotherapy, and have disease that is positive for the KRAS G12C mutation (confirmed by any standardized test). ~~81% of patients in the pivotal Codebreak 100 trial had received both platinum-based chemotherapy and Immune Checkpoint Inhibitor therapy.~~	Per FDA labeling
UM ONC_1440	Lumakras (sotorasib)	Negative change	Add inclusion criteria: B.Non-Small Cell Lung Cancer 2.NOTE: Per NCH Pathway & NCH Policy, Lumakras (sotorasib) is a non-Preferred drug for the first line treatment of KRAS G12C mutation NSCLC. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with Lumakras (sotorasib) compared to NCH Preferred regimens. Please refer to NCH Pathway for the preferred treatments recommended for first line treatment of NSCLC.	Per NCH Pathway exclusion
UM ONC_1441	Rybrevant (amivantamab-vmjw)	Positive change	Add inclusion criteria: B.Non-Small Cell Lung Cancer 1.Rybrevant (amivantamab-vmjw) may be used as monotherapy for members with locally advanced/metastatic/recurrent Non-Small Cell Lung Cancer, who have had disease progression on prior platinum- based therapy, with or without prior tyrosine kinase inhibitors/immunotherapy, and the cancer is positive for an EGFR exon 20 mutation (confirmed by a standardized test).	Per FDA labeling
UM ONC_1441	Rybrevant (amivantamab-vmjw)	Negative change	Add exclusion criteria: C.Dosing exceeds single dose limit of Rybrevant (amivantamab-vmjw) 1,400 mg (for weight ≥ 80 kg) or 1050 mg (for weight < 80 kg).	Per FDA labeling

Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
UM ONC_1442	Truseltiq (infigratinib)	Positive change	Add inclusion criteria: B.Cholangiocarcinoma 1.Truseltiq (infigratinib) ~~is a non-preferred drug for~~ may be used as monotherapy following disease progression on or after at least one prior systemic treatment for in FGFR2+,fibroblast growth factor receptor 2 (fusion or rearrangement) positive, unresectable/metastatic cholangiocarcinoma. ~~The Preferred option is Pemazyre (pemigatinib). 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).~~	Per FDA labeling
UM ONC_1442	Truseltiq (infigratinib)	Negative change	Add inclusion criteria: 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.	More Cost Effective Alternative(s)