Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
UM ONC_1072	Myeloid Growth Factors	Positive change	Add inclusion criteria: Add Fylnetra (pegfilgrastim-pbbk), new biosimilar to policy and criteria similar to all long acting MGF.	New FDA drug
UM ONC_1132	Rituxan Products	Negative change	Add inclusion criteria: B.CD-20 positive B-Cell Non-Hodgkin's Lymphomas (NHL) or Acute Lymphoblastic Leukemia (B-ALL) a.In relapsed/refractory DLBCL: Gemcitabine + vinorelbine +/- rituximab (NOT recommended for use per NCH policy)	Per Compendia Listing
UM ONC_1133	Erbitux (Cetuximab)	Negative change	Add exclusion criteria: C.Absence of documented KRAS/NRAS testing and results of such testing	Per FDA labeling
UM ONC_1181	Iron Products	Positive change	Remove inclusion criteria: b.The member is receiving (or has received within the last 8 weeks) myelosuppressive chemotherapy AND has chemotherapy induced anemia defined as a ~~Hgb of < 8 gm/dL or HCT < 24 (as recommended by NCH L1 pathway) OR~~Hgb < 10 g/dL or HCT < 30 (~~as required by NCH policy~~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 of< 30 ng/mL and/or a TSAT (transferrin saturation) of < 20% within the last 12 months. c. The member has anemia of chronic kidney disease defined by a GFR of < 60 mL/min AND a Hgb of <~~12~~10 gm/dL or HCT < 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 < 30 ng/mL and/or a TSAT (transferrin saturation) of < 20%.	Per Clinical Trial Analysis/Criteria
UM ONC_1181	Iron Products	Negative change	Add exclusion criteria: B.Dosing exceeds single dose limit of Infed (iron dextran) 100 mg or total replacement dose of 1,000 mg per course of treatment. C.Dosing exceeds single dose limit of Ferrlecit (sodium ferric gluconate) 125 mg or total replacement dose of 1,000 mg per course of treatment. D.Dosing exceeds single dose limit of Venofer (iron sucrose) 300 mg per dose or total replacement dose of 1,000 mg per course of treatment. D.E.Dosing exceeds single dose limit of Injectafer (ferric carboxymaltose) 750 mg or total replacement dose of 1,500 mg per course of treatment. E.F.Dosing exceeds single dose limit of Feraheme (ferumoxytol) 510 mg or total replacement dose of ~~2.04 gms~~ 1020 mg per course of treatment. F.G.Dosing exceeds single dose limit a nd total replacement dose of Monoferric (ferric derisomaltose) 1,000 mg.,	Per Compendia Listing
UM ONC_1215	Treanda/Bendeka/Belrapzo (bendamustine)	Positive change	Remove inclusion criteria: B.Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma 1. ~~Bendeka~~Treanda/Bendeka/Belrapzo (bendamustine) may be used in combination with rituximab (Truxima or Ruxience) as initial or subsequent therapy for members with CLL. 2. ~~NOTE 1: Unless there is prior history of hypersensitivity reactions or intolerance, the preferred bendamustine product is Bendeka over Belrapzo or Treanda for all indications and line of therapy.~~ ~~3.NOTE 2: Per NCH Pathway & NCH Policy, [bendamustine + rituximab +/- ibrutinib] is a Non-Preferred regimen for second line or subsequent treatment of CLL/SLL 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 second line or subsequent therapies in the treatment of CLL/SLL.~~ C.Non-Hodgkin's Lymphoma 1.Indolent B-Cell Lymphomas: ~~Bendeka~~ Treanda/Bendeka/Belrapzo (bendamustine) may be used for all clinical settings in the policy 4. ~~NOTE: Unless there is prior history of hypersensitivity reactions or intolerance, the preferred bendamustine product is Bendeka over Belrapzo or Treanda for all indications and line of therapy.~~	More Cost Effective Alternative(s)
UM ONC_1215	Treanda/Bendeka/Belrapzo (bendamustine)	Negative change	Add inclusion criteria: D.Small Cell Lung Cancer (SCLC) 1.Per NCH Pathway & NCH Policy, Treanda/Bendeka/Belrapzo (bendamustine) products are non-Preferred for the treatment of relapsed/refractory SCLC. 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 as subsequent therapy for SCLC.	Per NCH Pathway exclusion
UM ONC_1234	Zevalin (ibritumomab tiuxetan)	Negative change	Add inclusion criteria: B.Non-Hodgkin's Lymphoma (NHL) 1.The member has CD20 positive ~~B cell lymphoma specifically:~~ relapsed/refractory Follicular Lymphoma OR primary cutaneous diffuse large B-cell lymphoma leg type AND 2.Zevalin (ibritumomab tiuxetan) is being used in a member who has failed ≥ 2 prior lines of therapy, including chemo-immunotherapy (e.g., rituximab +/- CHOP/CVP/bendamustine) 3.NOTE: Per NCH Pathway & NCH Policy, Zevalin (ibritumomab tiuxetan) is a Non-Preferred drug for the treatment of relapsed or refractory Follicular Lymphoma, OR primary cutaneous diffuse large B-cell lymphoma leg type, Nodal Marginal Zone Lymphoma, Splenic Marginal Zone Lymphoma, Gastric and Non-gastric MALT Lymphoma. 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 regimens recommended in the above settings.	Per Compendia Listing
UM ONC_1324	Kymriah (tisagenlecleucel)	Negative change	Remove inclusion criteria: B.Acute Lymphoblastic Leukemia (ALL) c.Member has relapsed/refractory Philadelphia chromosome-negative B-ALL that has progressed after 2 cycles of a standard chemotherapy regimen for initial diagnosis OR after 1 cycle of standard chemotherapy for relapsed leukemia OR d.Member has relapsed/refractory Philadelphia chromosome-positive B-ALL that has progressed after failure of 2 prior regimens, including a TKI-containing regimen with Gleevec (imatinib), Bosulif (bosutinib), Sprycel (dasatinib), Tasigna (nilotinib), or Iclusig (ponatinib).	Per FDA labeling

UM ONC_1324	Kymriah (tisagenlecleucel)	Positive change	Add inclusion criteria: B.Acute Lymphoblastic Leukemia (ALL) c.Member has relapsed/refractory B- Cell ALL that has progressed after 2 lines of a standard chemotherapy regimen with or without a TKI; use with a TKI [e.g., Gleevec (imatinib)] is for members with Philadelphia chromosome-positive B-Cell ALL .	Per FDA labeling
UM ONC_1324	Kymriah (tisagenlecleucel)	Positive change	Add inclusion criteria: C.B-Cell Lymphomas 2.Kymriah (tisagenlecleucel) may be used in adult members with confirmed documentation of CD19 positive relapsed or refractory follicular lymphoma (Grade 1, 2, 3A) after 2 or more lines of systemic therapy, failure to maintenance therapy following at least two lines of therapy, and/or have failed autologous Hematopoietic stem cell transplantation (ASCT). For the above prior lines of therapy, these include chemoimmunotherapy with an anti-CD20 agent AND an alkylating agent (e.g., rituximab/obinutuzumab + bendamustine, rituximab/obinutuzumab + CHOP, rituxumab/obinutuzumab + CVP) .	New FDA Indication
UM ONC_1324	Kymriah (tisagenlecleucel)	Negative change	Add exclusion criteria: B.CD-19 positivity not confirmed and documented.	Per FDA labeling
UM ONC_1324	Kymriah (tisagenlecleucel)	Negative change	Remove exclusion criteria: J.Dosing exceeds single dose limit of Kymriah (tisagenlecleucel) ~~0.6 to~~ 6.0 x 108 CAR-positive viable T cells (for B-Cell Lymphomas); ~~0.1 to~~ 2.5 x 108 CAR-positive viable T cells (for ALL).	Per FDA labeling
UM ONC_1329	Yescarta (axicabtagene ciloleucel)	Negative change	Add exclusion criteria: E.Dosing exceeds single dose limit of Yescarta (axicabtagene ciloleucel) 2 × 108 CAR-positive viable T cells per kg body weight, up to a maximum total dose of 2×10^8 CAR-positive viable T cells.	Per FDA labeling
UM ONC_1332	Lutathera (Lutetium Lu 177 dotatete)	No Clinical Changes	N/A	N/A
UM ONC_1350	Vitrakvi (larotrectinib)	Positive change	Add inclusion criteria: B.NTRK positive Metastatic Solid Tumors 1.The member is an adult or pediatric member with ~~has~~ locally advanced or metastatic NTRK gene fusion-positive solid tumors, confirmed by an FDA companion diagnostic or laboratory testing (e.g., next-generation sequencing), and Vitrakvi (larotrectinib) may be used as a single agent.	Per FDA labeling
UM ONC_1350	Vitrakvi (larotrectinib)	Positive change	Remove inclusion criteria: B.NTRK positive Metastatic Solid Tumors 1.Members have an intolerance to/contraindication to therapy with Rozlytrek (entrectinib). 2.NOTE: The preferred agent, per NCH Policy & NCH Pathway for NTRK gene fusion positive recurrent, advanced, or metastatic tumors is Rozlytrek (entrectinib) over Vitrakvi (larotrectinib). This recommendation is based on a lack of Level 1 evidence showing better outcomes with Vitrakavi (larotrectinib) over Rozlytrek (entrectinib). Please refer to UM ONC_1367 Rozlytrek (entrectinib) policy.	Per NCH Pathway expansion
UM ONC_1351	Xospata (Gilteritinib)	No Clinical Changes	N/A	N/A
UM ONC_1353	Cablivi (caplacizumab-yhdp)	Negative change	Add exclusion criteria: C.Treatment exceeds the maximum duration limit of 30 days beyond the last plasma exchange. If ADAMTS13 activity levels remain suppressed following the last plasma exchange, Cablivi (caplacizumab-yhdp) may be extended for an additional 28 days (for a total of 2 treatment courses).	Per FDA labeling
UM ONC_1354	Daurismo (glasdegib)	Positive change	Remove inclusion criteria: B.Acute Myeloid Leukemia (AML) 1.Daurismo (glasdegib) may be used in combination with low dose cytarabine as ~~remission~~ treatment induction/post induction therapy in elderly or unfit members with AML.	Per FDA labeling
UM ONC_1354	Daurismo (glasdegib)	Positive change	Remove exclusion criteria: B.Daurismo (glasdegib) is being used as a single agent.	Per FDA labeling
UM ONC_1363	Nubeqa (darolutamide)	Positive change	Add inclusion criteria: B.Prostate Cancer 1.Nubeqa (darolutamide) may be used in combination with Androgen Deprivation Therapy (e.g., with an LHRH analog or following orchiectomy) ~~use is supported in members who meet~~ and ~~all~~ with ANY of the following criteria: a.Non-Metastatic Castration – Resistant Prostate cancer, (M0) disease, a PSA doubling time of 10 months or less, AND the absence of documented metastases to any site by conventional imaging (pelvic lymph nodes below aortic bifurcation < 2 cm are allowed), ~~AND~~OR b. ~~Nubeqa (darolutamide) will be used in combination with an LHRH analog (ADT - Androgen Deprivation Therapy).~~ b. Metastatic Castration Sensitive Prostate Cancer – in combination with Taxotere (docetaxel). The first dose of Taxotere (docetaxel) is started within 6 weeks after the start of Nubeqa (darolutamide) and may be given up to 6 cycles	New FDA Indication
UM ONC_1363	Nubeqa (darolutamide)	Positive change	Remove exclusion criteria: B.History of metastatic disease at any time or presence of detectable metastases.	Per FDA labeling
UM ONC_1367	Rozlytrek (entrectinib)	Positive change	Add inclusion criteria: C. Non-small cell lung cancer (NSCLC) 1.The member has recurrent, advanced, or metastatic NSCLC and Rozlytrek (entrectinib) may be used as a single agent in members with ROS-1 rearrangement-positive NSCLC ~~tumors with CNS metastases~~ as first-line or subsequent therapy	Per FDA labeling

UM ONC_1367	Rozlytrek (entrectinib)	Positive change	Add inclusion criteria: D.NTRK positive Metastatic Solid Tumors 1.Rozlytrek (entrectinib) may be used as monotherapy for adult and pediatric members 12 years of age and older with recurrent, advanced, or metastatic NTRK gene fusion-positive solid tumors, confirmed by an FDA companion diagnostic or laboratory testing (e.g., next-generation sequencing). Rozlytrek (entrectinib) may be used as first line or subsequent therapy if the member did not experienced disease progression with the same therapy or on another NTRK targeted therapy [e.g.,Vitrakvi (larotrectinib)]	New FDA Indication
UM ONC_1367	Rozlytrek (entrectinib)	Positive change	Remove inclusion criteria: 2.NOTE: The preferred agent, per NCH Policy and NCH Pathway, for first line therapy of ROS1 positive NSCLC with CNS metastases is Rozlytrek (entrectinib); for members without CNS metastases, the preferred agent is Zalkori (crizotinib). This recommendation is based on the lack of Level 1 evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes on rate of CNS progression with Zalkori (crizotinib) compared with Rozlytrek (entrectinib).	Per NCH Pathway expansion
UM ONC_1367	Rozlytrek (entrectinib)	Negative change	Add exclusion criteria: A.Rozlytrek (entrectinib) use after disease progression with the same regimen or other NTRK-targeted therapy [e.g.,Vitrakvi (larotrectinib)], unless the member has progressed on first line Rozlytrek (entrectinib) for ROS-1 rearrangement positive NSCLC; in this setting, Rozlytrek (entrectinib) may be continued as subsequent therapy if the member is asymptomatic or has disease that is limited to lung cancer with CNS progression as the exception. D. Treatment exceeds the maximum limit of 180~~90~~ (100 mg) and 90 (200 mg) tablets/month.	Per Compendia Listing
UM ONC_1379	Enhertu (fam-trastuzumab deruxtecan-nxki)	Positive change	Add inclusion criteria: D.Non-Small Cell Lung Cancer (NSCLC) 1.The member has unresectable or metastatic HER2 mutant (the presence of an activating HER-2 mutation) NSCLC and Enhertu (fam-trastuzumab deruxtecan-nxki) may be used following at least one prior platinum containing therapy (unless member has contraindication to such therapy) AND 2.The tumor is positive for an activating HER-2 mutation as confirmed by an FDA approved test.	New FDA Indication
UM ONC_1379	Enhertu (fam-trastuzumab deruxtecan-nxki)	Negative change	Add exclusion criteria: A.Enhertu (fam-trastuzumab deruxtecan-nxki) is being used during or after disease progression with the same regimen. B. Members with HER-2 protein overexpression as determined by IHC and members with HER-2 gene amplification (Rationale: Only patients with activating HER-2 mutations were enrolled in the published trial DESTINY 01 Lung trial that led to FDA approval; the trial is referenced below)	Per Clinical Trial Analysis/Criteria
UM ONC_1379	Enhertu (fam-trastuzumab deruxtecan-nxki)	Positive change	Remove exclusion criteria: B.The member has IHC score of 0 recurrent/metastatic breast cancer.	Per Clinical Trial Analysis/Criteria
UM ONC_1380	Gamifant (emapalumab-lzsg)	Positive change	Add inclusion criteria: B.Hemophagocytic lymphohistiocytosis (HLH) 1.The member is an adult or pediatric member (newborn and older)~~has~~with a diagnosis of primary hemophagocytic lymphohistiocytosis (HLH) AND Gamifant (emapalumab-lzsg) is being used in combination with dexamethasone for disease that is recurrent/refractory/progressing on conventional therapy/intolerant to conventional therapy. Conventional/first line therapy may include immunosuppressive regimens (e.g., corticosteroids, etoposide, cyclosporine, and/or stem cell transplantation).	Per FDA labeling
UM ONC_1380	Gamifant (emapalumab-lzsg)	Negative change	Add exclusion criteria: E.Treatment exceeds the maximum duration limit of 12 months post- transplant or 8 weeks if transplant was not performed.	Per FDA labeling
UM ONC_1383	Sylvant (siltuximab)	No Clinical Changes	N/A	N/A
UM ONC_1387	Unituxin (dinutuximab)	Positive change	Add inclusion criteria: B.Neuroblastoma 5.Unituxin (dinutuximab) is being used in combination with 13-cis-retinoic acid (isotretinoin), with or without granulocyte-macrophage colony-stimulating factor (sargramostim) or ~~, with or without~~ interleukin-2 (aldesleukin).	Per FDA labeling
UM ONC_1396	Koselugo (selumetinib)	Positive change	Remove inclusion criteria: B.Plexiform Neurofibromas (PN) c.The member is symptomatic (e.g. signs of hypertension, hydrocephalus, seizures, macrocephaly, skeletal changes, worsening visual changes, or cognitive and learning deficits).	Per Clinical Trial Analysis/Criteria
UM ONC_1396	Koselugo (selumetinib)	Negative change	Add exclusion criteria: C.Treatment exceeds the maximum limit of ~~60~~240 (10 mg) or 120 (25 mg) tablets/month.	Per FDA labeling
UM ONC_1407	Trodelvy (govitecan-hziy)	Positive change	Remove inclusion criteria: B.Breast Cancer ~~1.NOTE: Per NCH Policy and NCH Pathway, Trodelvy (sacituzumab govitecan-hzly) is the recommended agent for subsequent line (third line and beyond) therapy of metastatic, triple negative breast cancer.~~ 1.Trodelvy (sacituzumab govitecan-hzly) may be used as monotherapy, as a single agent, is supported when ALL of the following criteria are met: a.Member has recurrent/metastatic triple negative (ER/PR negative and /HER-2 negative) breast cancer AND b.Member has experienced disease progression on two or more lines of therapy and at least one of the therapies is for metastatic triple negative breast cancer. ~~1.NOTE: Risk of Febrile Neutropenia is 5% which does not require the use of myeloid growth factors as primary prophylaxis.~~ C.Urothelial Cancer 1.Trodelvy (sacituzumab govitecan-hzly) will may be used as monotherapy in members with locally advanced or metastatic urothelial cancer who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor [e.g., Keytruda (pembrolizumab), Opdivo (nivolumab), Tecentriq (atezolizumab), Bavencio (avelumab)].	Per FDA labeling

UM ONC_1413	Tecartus (brexucabtagene autoleucel)	Positive change	Remove inclusion criteria: C.B-Cell Acute Lymphoblastic Leukemia (B-Cell ALL), Confirmed CD-19 Positive 1.Tecartus (brexucabtagene autoleucel) may be used when the following criteria are met: a.Member is an adult, 18 years of age and older, with B-Cell Acute Lymphoblastic Leukemia with confirmed documentation of CD19 tumor expression (demonstrated in bone marrow or peripheral blood by flow cytometry) AND b.Member has experienced disease relapse at least 100 days from allogeneic stem cell transplantation (SCT) at the time of infusion OR c. Member has relapsed/refractory B-Cell ALL that has progressed after 2 lines of standard chemotherapy with or without TKI; use with a TKI [i.e., Gleevec (imatinib)} is for members with Philadelphia chromosome-positive B-Cell ALL. c. ~~Member has relapsed/refractory Philadelphia chromosome-negative B-ALL that has progressed after failure with at least 2 lines of systemic therapy, including Blincyto (blinatumomab) OR~~ ~~d.Member has relapsed/refractory Philadelphia chromosome-positive B-ALL that has progressed after failure with at least 2 different TKI-containing regimens with Gleevec (imatinib), Bosulif (bosutinib), Sprycel (dasatinib), Tasigna (nilotinib), or Iclusig (ponatinib).~~	Per FDA labeling
UM ONC_1413	Tecartus (brexucabtagene autoleucel)	Negative change	Add exclusion criteria: A.Tecartus (brexucabtagene autoleucel) is being used after disease progression on or after the same regimen or another CAR-T cell therapy directed towards CD19 antigen [e.g., Kymriah (tisagenlecleucel)~~, Breyanzi (lisocabtagene maraleucel)~~, Yescarta (axicabtagene ciloleucel)]. B.CD-19 positivity not confirmed and documented.	Per Clinical Trial Analysis/Criteria
UM ONC_1421	Breyanzi (lisocabtagene maraleucel)	Positive change	Add inclusion criteria: B.Diffuse Large B-Cell Lymphoma, confirmed CD-19 positive [Lymphoma sub-types include diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B]. 1.Breyanzi (lisocabtagene maraleucel) may be used for the treatment of adult members with relapsed or refractory large B-cell lymphoma (confirmed documentation of CD-19 positive tumor) after disease progression on/after ~~two~~ one or more lines of ~~systemic therapy, including~~ chemoimmunotherapy containing an anti-CD20 antibody and anthracycline (unless anthracyclines are contraindicated), who are not suitable for High Dose Chemotherapy + Hematopoientic Stem Cell Transplant, due to chemorefractory disease or any other reason~~Lymphoma sub-types include diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B.~~	New FDA Indication
UM ONC_1421	Breyanzi (lisocabtagene maraleucel)	Negative change	Add exclusion criteria: A.Disease progression while during or after taking Breyanzi (lisocabtagene maraleucel) or an anti-CD19 CAR-T cell therapy [e.g., Kymriah (tisagenlecleucel) or Yescarta (axicabtagene ciloleucel)]. B. CD-19 positivity not confirmed and documented.	Per Clinical Trial Analysis/Criteria