Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
UM ONC_1180	Immune Globulin (IG)	Positive change	Add inclusion criteria: B.Non- Familial/Acquired/Secondary Hypogammaglobulinemia (e.g., that is associated with Chronic Lymphocytic Leukemia, Multiple Myeloma, or post hematopoietic stem cell transplant, or CAR-T Cell Therapy 1.Intravenous Immune Globulin (IG) may be used in adult or pediatric members with Non-Familial/Acquired/Secondary Hypogammaglobulinemia (e.g., B-cell CLL/SLL, multiple myeloma, or is post Hematopoietic Stem Cell Transplant, or CAR-T cell therapy) and for any of the following requests: ~~with a documented history of recurrent bacterial infections AND a low IgG level (< 600 mg/dL) prior to intravenous immune globulin (IG) replacement.~~ a.For initial requests: The member has a documented IgG level < 600 mg/dL within the last 4 weeks AND/OR a documented history of frequent sino-bronchial, skin, other site bacterial infections, or is clinically felt to be immunocompromised. b.For continuation requests: i.The member has had a documented clinical benefit from IVIG therapy, e.g., reduced incidence of infections OR i.ii.The member has a history of an increase in recurrent infections within the last 6 months.	Per Clinical Trial Analysis/Criteria
UM ONC_1220	Arzerra (ofatumumab)	Negative change	Remove inclusion criteria: B.Chronic Lymphocytic Leukemia (CLL) 1.NOTE: Arzerra (ofatumumab) is not preferred for use in CLL. Per NCH Policy and NCH Pathways, the preferred anti-CD20 agents for use in CLL are Truxima (rituximab-abbs) & Ruxience (rituximab-pvvr). This recommendation is based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) to show superior outcomes with Arzerra (ofatumumab) over Truxima (rituximab-abbs) & Ruxience (rituximab-pvvr). 1.Arzerra (ofatumumab) may be used in members with CLL if all other available or recommended therapies have failed or are contraindicated.	Per NCH Pathway exclusion
UM ONC_1220	Arzerra (ofatumumab)	Positive change	Add inclusion criteria: 1.Arzerra (ofatumumab) may be used in members with one of the following criteria: a.In combination with chlorambucil for newly diagnosed CLL and the member has no history of prior treatment for CLL b.In combination with fludarabine + cyclophosphamide for relapsed/refractory CLL c.As monotherapy following response to prior therapy or as second line therapy for relapsed/refractory CLL.	Per FDA labeling
UM ONC_1220	Arzerra (ofatumumab)	Negative change	Add exclusion criteria: B.Dosing exceeds single dose limit of Arzerra (ofatumumab) 1,000 mg (for initial or extended treatment in CLL) or 2,000 mg (for relapsed/refractory CLL).	Per FDA labeling
UM ONC_1243	Nplate (romiplostim)	Negative change	Remove inclusion criteria: B.Chronic Idiopathic Thrombocytopenic Purpura (ITP) 1.The member has a diagnosis of relapsed/refractory chronic ITP AND the member has had an insufficient therapeutic response (defined by failure of platelet count to increase and stay above 30,000/mm3) OR intolerance to OR contraindications to corticosteroids AND/OR immunoglobulin (IVIG), AND/OR rituximab, AND/OR splenectomy.	Per FDA labeling
UM ONC_1243	Nplate (romiplostim)	Positive change	Add inclusion criteria: 1.The member is an adult or pediatric member 1 year of age and older with a diagnosis of relapsed/refractory chronic ITP and the initial request is for a platelet count of < 30 x 10^9/L AND the member has experienced therapeutic failure of, or has intolerance/contraindications to, corticosteroids, immunoglobulin (IVIG), AND/OR rituximab/splenectomy.	Per Clinical Trial Analysis/Criteria

Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
UM ONC_1244	Promacta (eltrombopag)	Positive change	Add inclusion criteria: B.Chronic Idiopathic Thrombocytopenic Purpura (ITP) 1.The member is an adult or pediatric member 1 year of age and older with a diagnosis of relapsed/refractory chronic ITP with an insufficient response to previous therapy including corticosteroids, immunoglobulins (IVIG), and Rituxan (rituximab)/splenectomy AND 2.The member has a A baseline platelet count of < ~~≤~~ 30 x 10^9/L. C.Thrombocytopenia in Chronic Hepatitis C Infection 1.Promacta (eltrombopag) may be used in a member with thrombocytopenia related to chronic hepatitis C infection and has a platelet count of < 50 x 10^9/L. D.Aplastic Anemia 1. The member is an adult or pediatric member 2 years of age and older with has severe aplastic anemia defined as an ANC count <500 /mcL, platelet count < 20 x 10^9/L,000/mm3, and an absolute reticulocyte count <60 x 10^9/L,000/mcL AND 2.Promacta (eltrombopag) may be used as a single agent or in combination with immunosuppression (e.g., ATG, cyclosporine, both or other immunosuppression)~~as a single agent.~~	Per Clinical Trial Analysis/Criteria
UM ONC_1244	Promacta (eltrombopag)	Negative change	Add exclusion criteria: B.Dosing exceeds single dose limit of Promacta (eltrombopag) 75 mg (for ITP), and 150 mg (for aplastic anemia) , 100 mg (for thrombocytopenia in chronic hepatitis C).	Per FDA labeling
UM ONC_1259	Gazyva (obinutuzumab)	Positive change	Add inclusion criteria: B.Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) ~~/ Follicular Lymphoma~~ 1.Gazyva (obinutuzumab) may be used in members with CD20 positive CLL/SLL/Follicular Lymphoma as a single agent or in combination with chemotherapy as any of the following: a.Initial therapy as a single agent OR in combination with chemotherapy OR b.Treatment of relapsed or refractory disease in combination with chemotherapy OR c.Maintenance therapy, as a single agent, for up to two years. 2. NOTE: Per NCH Pathway & NCH Policy, the following regimens are non-Pref erred 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 alternative treatments recommended for use in CLL/SLL. a.Initial or subsequent therapy with or without del (17p)/ TP53 mutation: Acalabrutinib + Obinutuzumab; Ibrutinib + Obinutuzumab. The above position is based on findings from randomized trials that do not show any additional benefit of adding a CD-20 antibody such as obinutuzumab to acalabrutinib or to ibrutinib, compared to single agent acalabrutinib or single agent ibrutinib. C.Follicular Lymphoma 1.Gazyva (obinutuzumab) may be used in members with CD20 positive Follicular Lymphoma as a single agent or in combination with chemotherapy as any of the following: a.Initial therapy, in combination with chemotherapy OR b.Treatment of relapsed or refractory disease in combination with chemotherapy OR c.Maintenance therapy, as a single agent, for up to two years. 2.NOTE: Per NCH Pathway & NCH Policy, Lenalidomide + Obinutuzumab is a non-Preferred regimen for initial treatment of Follicular 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 alternative treatments recommended for use in Follicular Lymphoma.	Per NCH Pathway exclusion and expansion
UM ONC_1259	Gazyva (obinutuzumab)	Negative change	Add exclusion criteria: C.Treatment with Gazyva (obinutuzumab) exceeds the total duration limit of 6 cycles (for initial therapy) and 2 years (for maintenance therapy).	Per FDA labeling
UM ONC_1259	Gazyva (obinutuzumab)	Positive change	Remove exclusion criteria: A.Disease progression while taking Gazyva (obinutuzumab) ~~or another anti-CD20 monoclona l antibody [e.g., Rituxan (rituximab)].~~	Per Clinical Trial Analysis/Criteria

Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
UM ONC_1263	Keytruda (pembrolizumab)	Negative change	Add inclusion criteria: D.Head and Neck Cancer b.NOTE: Per NCH Pathway & NCH Policy, Keytruda (pembrolizumab) + Erbitux (cetuximab) is a Non-Preferred regimen for the initial and subsequent treatment of non-nasopharyngeal cancers. 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 recurrent or metastatic Head and Neck Cancers.	Per NCH Pathway exclusion
UM ONC_1263	Keytruda (pembrolizumab)	Positive change	Remove inclusion criteria: F.Urothelial Carcinoma including Upper Urinary Tract Carcinoma and Carcinoma of Urethra 2.NOTE 1: Keytruda is a Non-Preferred drug for recurrent, non-muscle invasive urothelial carcinoma. This recommendation is based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) to support the use of Keytruda over other appropriate therapies for the above diagnosis.	Per NCH Pathway expansion
UM ONC_1263	Keytruda (pembrolizumab)	Negative change	Add inclusion criteria: H.Gastric Cancer or Esophageal and Esophagogastric Junction Cancers 2.Keytruda (pembrolizumab) will be used as any of the following: a.As first line therapy in combination with fluoropyrimidine and platinum containing chemotherapy ~~+/- trastuzumab (if HER positive)~~, AND CPS of 10 or higher. This position is supported by the lack of survival benefit of pembrolizumab monotherapy or pembrolizumab + chemotherapy for tumors expressing lower levels of PD-L1 OR a.b. As first line therapy in combination with fluoropyrimidine and platinum containing chemotherapy with trastuzumab for members with HER-2 positive disease, regardless of PD-L1 level. Q.Triple Negative Breast Cancer (TNBC) 1.Keytruda (pembrolizumab) may be used for the following: a.As a part of neoadjuvant therapy in combination wth chemotherapy and subsequent adjuvant therapy in a member with newly diagnosed high-risk early-stage TNBC (a tumor size >1 cm, ≤2 cm in diameter with nodal involvement, or tumor size >2 cm in diameter regardless of nodal involvement. NOTE Keytruda may be used as a part of the member'sadjuvant therapy ONLY if the member received pembrolizumab in the neoadjuvant setting)	Per Clinical Trial Analysis/Criteria
UM ONC_1270	Blincyto (blinatumomab)	Positive change	Remove inclusion criteria: B.Acute Lymphoblastic Leukemia (ALL) (Both Philadelphia chromosome positive and negative subtypes) 1.NOTE: NCH Pathway Preferred Regimen for MRD+ (measurable residual disease or minimal residual disease)/relapsed/refractory CD19 positive B-cell ALL is Blincyto (blinatumomab) over salvage chemotherapy and over Besponsa (inotuzumab ozogamicin). This recommendation is based on the trials that led to the approval of Blincyto (blinatumomab) which demonstrated improvements in OS and rates of remission in both Ph positive and negative ALL when compared to standard chemotherapy. Furthermore, there is no Level 1 evidence (randomized trials and or meta-analyses) to show that Besponsa (Inotuzumab Ozogamicin) is superior in terms of efficacy over Blincyto	Per NCH Pathway expansion
UM ONC_1270	Blincyto (blinatumomab)	Negative change	Add inclusion criteria:	Per NCH Pathway exclusion
UM ONC_1270	Blincyto (blinatumomab)	Negative change	Add exclusion criteria:	Per Clinical Trial Analysis/Criteria

Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
UM ONC_1303	Xermelo (telotristat ethyl)	Negative change	Add exclusion criteria: A.Disease/ symptom progression defined as a lack of improvement in symptoms of diarrhea associated with carcinoid syndrome, following 3 months on the maximum tolerated dose of Xermelo (telotristat ethyl).	Per FDA labeling
UM ONC_1306	Bavencio (avelumab)	Positive change	Add inclusion criteria: B.Merkel Cell Carcinoma (MCC) 1. The member is an adult OR pediatric member 12 years and older with has metastatic/recurrent/inoperable Merkel Cell Carcinoma, and Avelumab is being used as a single agent, with or without surgery and/or radiation therapy. C.Metastatic Urothelial Carcinoma including carcinomas of the upper Genito-Urinary Tract & Urethra 1. Bavencio (avelumab) may be used as a single agent, as second line/subsequent therapy following prior chemotherapy, and in a member with locally advanced or metastatic urothelial carcinoma including the upper genito-urinary tract/urethra. 2.Maintenance Therapy after systemic chemotherapy: Member has locally advanced or metastatic urothelial carcinoma and has experienced CR/PR/SD with 4-6 cycles of first line platinum (cisplatin/carboplatin) + ~~gemcitabine~~ containing chemotherapy, AND Bavencio (avelumab) is being used as a single agent.	Per FDA labeling
UM ONC_1306	Bavencio (avelumab)	Positive change	Remove inclusion criteria: C.Metastatic Urothelial Carcinoma including carcinomas of the upper Genito-Urinary Tract & Urethra 3.NOTE: Per NCH Policy & NCH Pathway, Bavencio (avelumab) is a non-preferred drug for the treatment of relapsed/refractory Urothelial Carcinoma. Keytruda (pembrolizumab) is the preferred agent per NCH Policy & NCH Pathway, over other Check-Point Inhibitors (PD-1 or PD-L1 inhibitors i.e., Opdivo, Tecentriq, Bavencio, Imfinzi), for second line therapy of metastatic urothelial carcinoma following platinum containing therapy, or for first line therapy if platinum-based therapy is contraindicated regardless of the PD-L1 status; the member should not have received prior therapy with a Check-Point Inhibitor. This recommendation is based on the fact that only Keytruda has Level 1 evidence in this setting showing a survival advantage. D.Renal Cell Carcinoma (RCC) 1.Bavencio (avelumab) may be used in combination with Inlyta (axitinib) as first line therapy in a member with advanced or metastatic RCC.	Per NCH Pathway exclusion/expansion
UM ONC_1323	Idhifa (enasidenib)	Positive change	Add inclusion criteria: B.Acute Myeloid Leukemia (AML) with Positive IDH-2 mMutation 1.The member has a confirmed diagnosed of IDH-2 mutation positive (using any FDA approved test) AML and Idhifa (enasidenib) is being used either as a single agent for relapsed or refractory disease OR 2.Idhifa (enasidenib) is being used as first line therapy in IDH2 mutation + AML in combination with either azacitidine or decitabine, in a member who is not a suitable candidated for standard induction chemotherapy.	Per Compendia Listing
UM ONC_1323	Idhifa (enasidenib)	Positive change	Remove inclusion criteria: 2.As treatment induction when the member is not a candidate for intensive remission induction therapy or declines intensive therapy OR as post-remission therapy OR for relapsed or refractory disease.	Per FDA labeling
UM ONC_1325	Mylotarg (gemtuzumab ozogamicin)	Positive change	Add inclusion criteria: B.Acute Myeloid Leukemia (AML) 1.The member has CD33-positive AML and Mylotarg (gemtuzumab ozogamicin) is being used as a single agent OR in combination with chemotherapy for members with newly diagnosed AML (age 1 month and older)/relapsed/refractory AML (age 2 years and older) who have not received Mylotarg previously.	Per FDA labeling

Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
UM ONC_1325	Mylotarg (gemtuzumab ozogamicin)	Negative change	Add inclusion criteria: 2.NOTE: Per NCH Pathway & NCH Policy, the following regimens are Non-Preferred ba sed 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 alternative regimens: a.Induction therapy, <60 years of age: Fludarabine + HiDAC + idarubicin + G-CSF + gemtuzumab ozogamicin b.Induction/Consolidation therapy, ≥ 60 years of age: Single agent Mylotarg (gemtuzumab ozogamicin) a.c.Relapsed/refractory ≥ 60 years of age: Single agent Mylotarg (gemtuzumab ozogamicin).	Per NCH Pathway exclusion
UM ONC_1325	Mylotarg (gemtuzumab ozogamicin)	Negative change	Add exclusion criteria: A.Disease progression on or following Mylotarg (gemtuzumab ozogamicin) or Mylotarg (gemtuzumab ozogamicin) containing regimen.	Per Clinical Trial Analysis/Criteria
UM ONC_1334	Doptelet (avatrombopag)	Negative change	Add exclusion criteria: A.Disease progression defined as a lack in rise of Platelet counts, from baseline, after 4 weeks at the maximum tolerated dose AND the member continued to receive blood transfusions while on Doptelet (avatrombopag).	Per Clinical Trial Analysis/Criteria
UM ONC_1340	Tibsovo (ivosidenib)	Positive change	Add inclusion criteria: B.Acute Myeloid Leukemia (AML) 1.The member has AML with a documented IDH1 gene-mutation as detected by an FDA approved test, e.g. Abbott RealTime IDH1 Assay AND Tibsovo (ivosidenib) may be used as monotherapy or in combination with Vidaza (azacitdine) for newly diagnosed AML OR as monotherapy for relapsed/refractory AML.	New FDA Indication
UM ONC_1340	Tibsovo (ivosidenib)	Positive change	Remove inclusion criteria: 2.Tibsovo (ivosidenib) may be used as a single agent as ANY of the following: a.Induction/initial treatment, b.Post-remission/consolidation therapy following response to induction/initial treatment c.a.For relapsed/refractory AML	Per FDA labeling
UM ONC_1340	Tibsovo (ivosidenib)	Negative change	Add exclusion criteria: A.Disease progression on or following Tibsovo (ivosidenib) or Tibsovo (ivosidenib) containing regimen.	Per Clinical Trial Analysis/Criteria
UM ONC_1343	Mulpleta (lusutrombopag)	Negative change	Add exclusion criteria: A.Disease progression defined as a lack in rise of Platelet counts, from baseline, after 4 weeks at the maximum tolerated dose AND the member continued to receive blood transfusions while on Mulpleta (lusutrombopag).	Per Clinical Trial Analysis/Criteria
UM ONC_1378	Ayvakit (avapritinib)	Positive change	Add inclusion criteria: B.Gastrointestinal Stromal Tumor (GIST) 1.The member has unresectable or metastatic GIST with a documented platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations, and Ayvakit (avapritinib) may be used as monotherapy.	Per Compendia Listing
UM ONC_1378	Ayvakit (avapritinib)	Negative change	Add inclusion criteria: B.Gastrointestinal Stromal Tumor (GIST) 2.NOTE: Per NCH Pathway & NCH Policy, Ayvakit (avapritinib) is a non-Preferred drug. Gleevec (imatinib) is the preferred NCH L1 pathway for PDGFRA exon 18 mutation positive (except for D842V mutation) unresectable or metastatic GIST. For PDGFRA D842V mutation positive GIST, Qinlock (ripretinib) is the preferred treatment over Ayvakit (avapritinib) in this setting.	Per NCH Pathway exclusion

Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
UM ONC_1381	Padcev (enfortumab vedotin-ejfv)	Positive change	Add inclusion criteria: a.Have previously received Check Point Inhibitor therapy (PD-1 or PD-L1 inhibitors) and a platinum (cisplatin/carboplatin)-containing chemotherapy regimen in the neoadjuvant/adjuvant, locally advanced, or metastatic setting,	Per Compendia Listing
UM ONC_1409	Pediatric Treatment Requests			
UM ONC_1410	Inqovi (decitabine and cedazuridine)	Positive change	Add inclusion criteria: B.Myelodysplastic Syndromes (MDS) 1.The member has MDS and Inqovi may be used as an oral fixed dose combination therapy (decitabine 35 mg and cedazuridine 100 mg).	Per FDA labeling
UM ONC_1410	Inqovi (decitabine and cedazuridine)	Negative change	Add inclusion criteria: B.Myelodysplastic Syndromes (MDS) 2.NOTE: Per NCH Policy and NCH Pathway, Inqovi (decitabine and cedazuridine) is a non-preferred d rug for the treatment of MDS. The preferred agents are Vidaza (azacitidine) and Dacogen (decitabine).This position is based on the lack of Level 1 evidence (randomized phase III trials and or meta-analyses) to show superior outcomes (any of the following: a.Progression Free Survival b. Overall Survival c. Time to progression to Acute Leukemia) with Inqovi over Vidaza or Dacogen	Per NCH Pathway exclusion
UM ONC_1410	Inqovi (decitabine and cedazuridine)	Positive change	Remove inclusion criteria: 2.Meta-analyses have not shown the superiority of Dacogen (decitabine) over Vidaza (azacitidine) for PFS and OS in MDS (any risk group of MDS)1. 3.Inqovi (decitabine and cedazuridine) is an oral formulation of decitabine. It has not been shown to be superior to conventional Vidaza (azacitidine) in MDS (any risk group) for the following clinical end points a.Progression Free Survival b.Overall Survival c.Time to progression to Acute Leukemia.	Per Clinical Trial Analysis/Criteria
UM ONC_1426	Pepaxto (melphalan flufenamide)	Negative change	FDA and manufacturer withdrew/discontinue from the market October 22, 2021. Will archive policy.	Archive policy