Policy #	Policy Name	Brief Description of Policy Change
UM ONC_1041	LHRH agonists and antagonist	Remove inclusion criteria: B.Prostate Cancer NOTE 1: Lupron Depot/Eligard (J9217 leuprolide 7.5 mg or 22.5 mg) are the preferred LHRH analogs in members with prostate cancer for all curative and palliative settings. NOTE 2: For ADT- Androgen Deprivation Therapy- in prostate cancer, the oral LH-RH analog Orgovyx (relugolix) is not recommended per NCH Pathway and NCH Policy. Preferred alternatives are described above in Note #1. The recommendation is based on a lack of Overall Survival benefit with Orgovyx (relugolix) over Lupron Depot/Eligard (leuprolide).
UM ONC_1041	LHRH agonists and antagonist	Add inclusion criteria: B.Prostate Cancer 1.Per NCH pathway & NCH policy the preferred LHRH analogs for the treatment of prostate cancer are Trelstar (J3315 triptorelin) and Lupron Depot/Eligard (J9217 leuprolide 7.5 mg, 22.5 mg, 30 mg, or 45 mg. 2.The non-preferred LHRH analogs are Lupron Depot (J1950 3.75 mg or 11.25 mg), Camcevi SC Depot (J1952 leuprolide mesylate), Zoladex (J9202 goserelin), Firmagon (J9155 degarelix), Vantas (J9225 histrelin), and Orgovyx (J8999 relugolix). 3.The above recommendations are based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) showing superior outcomes with one LHRH analog over another in the treatment of prostate cancer, unless the member is intolerant to, has a contraindication to, or failure on the preferred LHRH analogs.
UM ONC_1041	LHRH agonists and antagonist	Add inclusion criteria: C.Breast Cancer 1.NOTE: T relstar (J3315 triptorelin) and Lupron Depot/Eligard (J9217 leuprolide 7.5 mg or 22.5 mg) are the preferred LHRH analogs over Lupron Depot (J1950 3.75 mg or 11.25 mg) and Zoladex (J9202 goserelin). in members with ER/PR + breast cancer for all curative and palliative settings. This recommendation is based on the lack of Level 1 evidence (randomized trial and or meta-analysis) showing superior outcomes with one LHRH analog over another, unless the member is intolerant to, has a contraindication to, or failure on the preferred LHRH analogs.
UM ONC_1041	LHRH agonists and antagonist	Add inclusion criteria: D.Fertility Preservation in Women Undergoing Cytotoxic Chemotherapy 1.NOTE: Trelstar (J3315 triptorelin) and Lupron Depot/Eligard (J9217 leuprolide 7.5 mg or 22.5 mg) are the preferred LHRH analogs over Lupron Depot (J1950 3.75 mg or 11.25 mg) and Zoladex (J9202 goserelin) and may be used in female members who are receiving chemotherapy and desire fertility preservation. This recommendation is based on the lack of Level 1 evidence (randomized trial and or meta-analysis) showing superior outcomes with one LHRH analog over another, unless the member is intolerant to, has a contraindication to, or failure on the preferred LHRH analogs.
UM ONC_1041	LHRH agonists and antagonist	Remove inclusion criteria: A.Use of the non-preferred LHRH analogs Trelstar (triptorelin), Firmagon (degarelix), J1950 leuprolide (e.g., 3.75 mg or 11.25 mg), or Orgovyx (relugolix) product instead of the preferred Lupron Depot/Eligard (J9217 leuprolide 7.5 mg or 22.5 mg).
UM ONC_1041	LHRH agonists and antagonist	Add exclusion criteria: C.Camcevi SC Depot (J1952 leuprolide mesylate), Firmagon (J9155 degarelix), Vantas (J9225 histrelin), or Orgovyx (J8999 relugolix) is being used in members with breast cancer or for fertility preservation in women undergoing cytotoxic chemotherapy E.Treatment exceeds the maximum limit of Orgovyx (relugolix) 30 (120 mg) tablets per month. D.Dosing exceeds single dose limit of Lupron Depot/Eligard (Lleuprolide) IM depot 45 mg every ~~12~~ 6 months
UM ONC_1063	Oncaspar (pegaspargase)	Remove inclusion criteria: B.Acute Lymphocytic Leukemia (ALL) including T-Cell Lymphoma/Leukemia 2. Rationale: AALL07P4 clinical trial results demonstrated no substantial difference in event free survival using Asparlas in comparison to patients treated with pegaspargase in the treatment of ALL. Please refer to UM ONC_1352 Asparlas (calaspargase pegol-mknl) policy.
UM ONC_1063	Oncaspar (pegaspargase)	Add inclusion criteria: B.Acute Lymphocytic Leukemia (ALL) including T-Cell Lymphoma/Leukemia 1.NOTE: Per NCH Policy & NCH Pathway, Oncaspar (pegasparagase) and Asparlas (calaspargase pegol-mknl) is are preferred over Erwinaze (erwinia asparaginase) and Rylaze (erwinia asparaginase recombinant) for use in for all subtypes of ALL as a part of anti-leukemia therapy. This recommendation is based on the lack of Level 1 evidence (randomized clinical trials and/or meta-analyses) that shows superior outcomes of Erwinia products over Oncaspar (pegasparagase) and Asparlas (calaspargase pegol-mknl).
UM ONC_1063	Oncaspar (pegaspargase)	Add exclusion criteria: A.Disease progression on or after an Oncaspar (pegaspargase) containing regimen.

Policy #	Policy Name	Brief Description of Policy Change
UM ONC_1072	Myeloid Growth Factors (Neupogen, Granix, Leukine, Zarxio, Neulasta/Fulphila)	Add inclusion criteria: B.Prophylaxis/Prevention of Febrile Neutropenia from Chemotherapy. 1. NOTE: 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. 1.2.The member has a solid tumor or non-myeloid malignancy and is receiving MGF for any of the following: a.MGF is being used for chemotherapy with high-risk (> 20%) for febrile neutropenia (please refer to attachment B for a list of cytotoxic drugs with high-risk for febrile neutropenia)
UM ONC_1238	Kadcyla (ado-trastuzumab emtansine)	Remove inclusion criteria: HER-2 Positive Breast Cancer- remove disease characteristics table
UM ONC_1242	Jakafi (ruxolitinib)	Add inclusion criteria: B.Myelofibrosis 2.Jakafi (ruxolitinib) may be used as monotherapy in a member with any of the following: primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis. C.Polycythemia Vera 1.The member has polycythemia vera and has had an inadequate response to or is intolerant to hydroxyurea. Jakafi (ruxolitinib) will be used as monotherapy.
UM ONC_1272	Ibrance (palbocidib)	Add inclusion criteria: B.Breast Cancer 1.Ibrance (palbociclib) may be used in members with ER/PR positive and HER2 negative recurrent or metastatic breast cancer as follows: a.In combination with an aromatase inhibitor (in postmenopausal/premenopausal women treated with ovarian oblation/suppression women) OR b.In combination with fulvestrant in postmenopausal/premenopausal women treated with ovarian oblation/suppression, if CDK4/6 inhibitor [e.g., Kisqali (ribociclib), Verzenio (abemaciclib)] was not previously used.
UM ONC_1274	Opdivo (nivolumab)	Add inclusion criteria: C.Non-Small Cell Lung Cancer (NSCLC) he recommended regimens are: [carboplatin/cisplatin + pemetrexed + pembrolizumab] for non-squamous NSCLC and [carboplatin/cisplatin + paclitaxel + pembrolizumab] for squamous NSCLC. D.Renal Cell Carcinoma a.As first line therapy as monotherapy or in combination with Yervoy (ipilimumab) for IMDC Intermediate or Poor Risk disease. E.Hodgkin's Lymphoma 1.NOTE: The preferred Immune Checkpoint Inhibitor, for members with relapsed/refractory Hodgkin's Lymphoma (including members who failed or are not candidates for autologous stem cell transplant) is Keytruda (pembrolizumab). This recommendation is based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) to show superior outcomes with Opdiivo (nivolumab) compared to Keytruda (pembolizumab). Please refer to UM ONC_1263 Keytruda (pembrolizumab) policy. I.Esophageal Carcinoma c.Opdivo (nivolumab) will be used as a single agent as ~~third~~ second line or subsequent therapy, regardless of PD-L1 status. J.Malignant Pleural Mesothelioma 1. The recommended dose of Opdivo (nivolumab) is 360 mg every 3 weeks + Yervoy (ipilimumab) ~~is dosed at~~ 1 mg/kg every 6 weeks until disease progression, ~~or~~ unacceptable toxicities, or up to 24 months of therapy, in the above setting. 3.Opdivo (nivolumab) may be used as monotherapy or in combination with Yervoy (ipilimumab) (if was not previously used) in metastatic/unresectable malignant pleural mesothelioma, in the 2nd line/subsequent line setting, regardless of the histologic sub-type, in members who experience disease progression on prior first line chemotherapy.

Policy #	Policy Name	Brief Description of Policy Change
UM ONC_1324	Kymriah (tisagenlecleucel)	Add inclusion criteria: B.Acute Lymphoblastic Leukemia (ALL) 1.Kymriah (tisagenlecleucel) is being used as monotherapy when the following criteria are met: 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). C.B-Cell Lymphomas 1.Kymriah (tisagenlecleucel) may be used as monotherapy for members who are 18 years of age or older, with Diffuse Large B-Cell Lymphoma, transformed Follicular Lymphoma, high-grade B-cell lymphoma with MYC rearrangement plus rearrangement of BCL2, BCL6, or both genes (i.e., double- or triple-hit lymphoma) with confirmed documentation of CD19 tumor expression. AND 2.Members must have previously received at least two lines of therapy, including rituximab and an anthracycline, unless anthracyclines are contraindicated (for DBCL) AND 3.Either having failed autologous Hematopoietic stem cell transplantation (ASCT) or being ineligible for or not consenting to ASCT.
UM ONC_1324	Kymriah (tisagenlecleucel)	Remove exclusion criteria: 2.Absolute lymphocyte count (ALC) > 300/uL 4.Baseline oxygen saturation > 91% on room air.
UM ONC_1324	Kymriah (tisagenlecleucel)	Add exclusion criteria: I.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). J.Does not exceed duration limit as one time administration.
UM ONC_1329	Yescarta (axicabtagene ciloleucel)	Add exclusion criteria: E.Dosing exceeds single dose limit of Yescarta (axicabtagene ciloleucel) 2 × 108 CAR-positive viable T cells per kg body weight,
UM ONC_1329	Yescarta (axicabtagene ciloleucel)	Remove exclusion criteria: 2.Absolute lymphocyte count (ALC) ≥ 100/uL 5.Baseline oxygen saturation > 92% on room air.
UM ONC_1352	Asparlas (calaspargase pegol-mknl)	Remove inclusion criteria: B.Acute Lymphoblastic Leukemia (ALL) 1.The member is ≤21 years of agewith a diagnosis of ALL AND 2.NOTE: Per NCH Policy & NCH Pathway, Asparlas (calaspargase pegol-mknl) is preferred over Oncaspar (pegasparagase) for use in ALL as a part of anti-leukemia therapy. Rationale: AALL07P4 clinical trial results demonstrated no substantial difference in event free survival
UM ONC_1352	Asparlas (calaspargase pegol-mknl)	Add inclusion criteria: B.Acute Lymphoblastic Leukemia (ALL) 1.NOTE: Per NCH Policy & NCH Pathway, Asparlas (calaspargase pegol-mknl) and Oncaspar (pegasparagase) are preferred over Erwinaze (erwinia asparaginase) and Rylaze (erwinia asparaginase recombinant) for all subtypes of ALL as a part of anti-leukemia therapy. This recommendation is based on the lack of Level 1 evidence (randomized clinical trials and/or meta-analyses) that shows superior outcomes of Erwinia products over Oncaspar (pegasparagase) and Asparlas (calaspargase pegol-mknl). 2.Asparlas (calaspargase pegol-mknl) will be used in a member ≤21 years of age with a diagnosis of ALL, as part of a multi-agent chemotherapy regimen, and as therapy for induction/consolidation/relapsed/refractory disease.
UM ONC_1352	Asparlas (calaspargase pegol-mknl)	Remove exclusion criteria: A.Asparlas (calaspargase pegol-mknl) is being used after disease progression with the same regimen, Oncaspar (pegasparagase)containing regimen. or Erwinaze (Asparaginase Erwinia chrysanthemi).
UM ONC_1352	Asparlas (calaspargase pegol-mknl)	Remove exclusion criteria: A.Asparlas (calaspargase pegol-mknl) is being used after disease progression with an Asparlas (calaspargase pegol-mknl) containing regimen.
UM ONC_1361	Erwinaze and Rylaze (asparaginase Erwinia chrysanthemi)	Remove inclusion criteria: B.Acute Lymphoblastic Leukemia (ALL) 1.NOTE: Asparlas (calaspargase pegol-mknl) is preferred over Erwinaze and Rylaze (asparaginase Erwinia chrysanthemi and recombinant-rywn) in the treatment of ALL, unless the member has a history of a hypersensitivity reaction or other adverse effects from Asparlas (calaspargase pegol-mknl). Please refer to UM ONC_1352 Asparlas (calaspargase pegol-mknl) policy.

Policy #	Policy Name	Brief Description of Policy Change
UM ONC_1361	Erwinaze and Rylaze (asparaginase Erwinia chrysanthemi)	Add inclusion criteria: B.Acute Lymphoblastic Leukemia (ALL) 1.NOTE: Per NCH Policy & NCH Pathway, Oncaspar (pegasparagase) and Asparlas (calaspargase pegol-mknl) are preferred over Erwinaze (erwinia asparaginase) and Rylaze (erwinia asparaginase recombinant) for all subtypes of ALL as a part of anti-leukemia therapy. This recommendation is based on the lack of Level 1 evidence (randomized clinical trials and/or meta-analyses) that shows superior outcomes of Erwinia products over Oncaspar (pegasparagase) and Asparlas (calaspargase pegol-mknl). Erwinaze (erwinia asparaginase) and Rylaze (erwinia asparaginase recombinant) may be considered for hypersensitivity reactions to Oncaspar (pegasparagase) and Asparlas (calaspargase pegol-mknl). 2.Erwinaze and Rylaze (asparaginase Erwinia chrysanthemi and recombinant-rywn) may be used in members with Philadelphia chromosome-negative ALL/Philadelphia chromosome positive ALL as a part of a multi-agent chemotherapy regimen and as therapy for induction/consolidation/relapsed/refractory disease, unless the member has a history of hypersensitivity reaction or other adverse effects from Oncaspar (pegasparagase) or Asparlas (calaspargase pegol-mknl).
UM ONC_1361	Erwinaze and Rylaze (asparaginase Erwinia chrysanthemi)	Add exclusion criteria: A.Erwinaze and Rylaze (asparaginase Erwinia chrysanthemi and recombinant- rywn) is being used after disease progression with ~~the same regimen~~ one or the other Erwinia product.
UM ONC_1413	Tecartus (brexucabtagene autoleucel)	Add inclusion criteria: C.Acute Lymphoblastic Leukemia (ALL) 1.Tecartus (brexucabtagene autoleucel) may be used as monotherapy 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).
UM ONC_1413	Tecartus (brexucabtagene autoleucel)	Add exclusion criteria: D.Dosing exceeds single dose limit of Tecartus (brexucabtagene autoleucel) 2 × 108 CAR-positive viable T cells (for Mantle Cell Lymphoma); 1 × 108 CAR-positive viable T cells (for ALL). 1.Serum ALT/AST (hepatic transaminases) ≤ 2.5 times the upper limit of normal or total bilirubin ≤ 1.5mg/dL
UM ONC_1413	Tecartus (brexucabtagene autoleucel)	Remove exclusion criteria: 2.Absolute lymphocyte count (ALC) ≥ 100 cells/uL F.The member does not have adequate hepatic, renal, and cardiac , ~~and pulmonary~~ function 3.EKG has no clinically significant findings 4.Baseline oxygen saturation > 92% on room air. F.Prior Allogeneic hematopoietic stem cell transplant (HSCT).
UM ONC_1421	Breyanzi (lisocabtagene maraleucel)	Remove exclusion criteria: 4.Baseline oxygen saturation > 91% on room air.
UM ONC_1429	Abecma (idecabtagene vicleucel)	Remove exclusion criteria: 2.Absolute lymphocyte count (ALC) ≥ 100/uL 4.Baseline oxygen saturation ≥ 92% on room air.
UM ONC_1429	Abecma (idecabtagene vicleucel)	Add exclusion criteria: H.Dosing exceeds single dose limit of Abecma (idecabtagene vicleucel) 460 × 106 CAR-positive T cells.