

Policy	Drug(s)	Type of Change	Brief Description of Policy Change
UM ONC_1035	5HT3 Receptor	Formatting	n/a
UM ONC_1313	Alunbrig (brigatinib)	Negative change	<p>Add inclusion criteria: NSCLC</p> <p>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 :</p> <p>a.First line therapy if there is intolerance or contraindication to alectinib, OR</p> <p>b. Second line/subsequent therapy if there has been disease progression on prior crizotinib therapy</p>
UM ONC_1313	Alunbrig (brigatinib)	Positive change	<p>Remove inclusion criteria:</p> <p>Brigatinib may be used as a single agent for members for ALK + metastatic/recurrent Non Small Cell Lung Cancer, when the disease has progressed on prior crizotinib therapy.</p>
UM ONC_1028	Avastin (bevacizumab)/Mvasi (bevacizumab- awwb)/Zirabev (bevacizumab-bvzr)	Positive change	<p>Remove inclusion criteria: 2. Colorectal Cancer- ii. As initial therapy in combination with infusion 5-FU/LV or capecitabine for members who cannot tolerate intensive therapy</p>
UM ONC_1028	Avastin (bevacizumab)/Mvasi (bevacizumab- awwb)/Zirabev (bevacizumab-bvzr)	Positive change	<p>Remove inclusion criteria: 3. Non-Small Cell Lung Cancer (NSCLC)</p> <p>3. NOTE: Bevacizumab- based regimens are non-preferred per NCH Policy &amp; NCH Pathway for metastatic non-squamous Non-Small Cell Lung Cancer. Please refer to the NCH Pathway document for the current recommended regimens in the above cancer type/stage.</p>

UM ONC_1028	Avastin (bevacizumab)/Mvasi (bevacizumab- awwb)/Zirabev (bevacizumab-bvzr)	Positive change	<p>Add inclusion criteria:</p> <p>4. Glioblastoma- in any line of therapy for this disease</p> <p>5. Renal Cell Carcinoma - NOTE: Bevacizumab is a non-preferred drug for metastatic clear cell Renal Cell Carcinoma; i. As single-agent <b>for members who have experienced disease progression on an oral TKI ( e.g. pazopanib) AND a checkpoint inhibitor ( e.g. pembrolizumab)</b> subsequent therapy for clear cell histology; ii. A single-agent for non-clear cell histology, <b>in any line of therapy.</b></p> <p>6. Cervical Cancer -NOTE: Bevacizumab + Cisplatin/Carboplatin + Paclitaxel is the preferred regimen for initial/first line therapy for metastatic cervical carcinoma</p> <p>7. Hepatocellular Carcinoma - Member has metastatic/inoperable/advanced hepatocellular carcinoma and bevacizumab will be used in combination with atezolizumab for initial therapy.</p>
UM ONC_1204	Caprelsa (vandetarib)	Positive change	<p>Add inclusion criteria: 2. Thyroid Cancer Caprelsa (vandetanib) may be used for members with any of the following:</p> <p>i. Unresectable or metastatic medullary thyroid cancer OR</p> <p>ii. Unresectable or metastatic papillary, follicular, or Hurthle cell thyroid cancer and the member is refractory to radioactive iodine treatment (if radioactive iodine treatment is appropriate).</p>
UM ONC_1204	Caprelsa (vandetarib)	Positive change	<p>Remove inclusion criteria: 2. Non-Small Cell Lung Cancer (NSCLC)</p> <p>a. Caprelsa (vandetanib) is being used as a single agent in members with RET gene rearrangements.</p>

UM ONC_1204	Caprelsa (vandetanib)	Positive change	<p>Remove exclusion criteria:</p> <ol style="list-style-type: none"> <li>1. Caprelsa (vandetanib) is being used concurrently with other tyrosine kinase inhibitors.</li> <li>2. Caprelsa (vandetanib) is being used in members with indolent, asymptomatic, or slowly progressing disease.</li> <li>3. Concomitant use with Torisel (temsirolimus) or Afinitor (everolimus) is not recommended at this time due to lack of evidence supporting safety and efficacy.</li> </ol>
UM ONC_1261	Cyramza (ramucirumab)	Negative change	<p>Add inclusion criteria: 3. Non-Small Cell Lung Cancer (NSCLC)/ Colorectal Carcinoma/Hepatocellular Carcinoma</p> <ol style="list-style-type: none"> <li>a. Cyramza (ramucirumab) is a non-preferred drug for the treatment of all the above cancer types. Please refer to the NCH Pathway document for recommended/preferred regimens/agents for the above cancer types.</li> </ol>
UM ONC_1334	Doptelet (avatrombopag)	Positive change	<p>Remove inclusion criteria: a. chronic liver disease with a Model For End-stage Liver Disease (MELD) score less than or equal to 24 c. The member is at high risk for bleeding</p>
UM ONC_1334	Doptelet (avatrombopag)	Positive change	<p>Add inclusion criteria: 3. Idiopathic Thrombocytopenia Purpura (ITP)</p> <ol style="list-style-type: none"> <li>a. The member has a diagnosis of relapsed/refractory chronic ITP AND</li> <li>b. The member has insufficient response (defined by failure of platelet count to increase and stay above 30,000), intolerance, or contraindications to corticosteroids, immunoglobulins (IVIG), AND rituximab AND</li> <li>c. Platelet count <math>\leq</math> 30,000/mm<sup>3</sup>.</li> </ol>

UM ONC_1334	Doptelet (avatrombopag)	Negative change	Add exclusion criteria : Use after failure with Mulpleta (lusutrombopag) for thrombocytopenia in chronic liver disease .
UM ONC_1334	Doptelet (avatrombopag)	Positive change	Remove exclusion criteria: 2. Concurrent use with heparin, warfarin, nonsteroidal anti-inflammatory drugs (NSAID), aspirin, verapamil, antiplatelet therapy with ticlopidine or glycoprotein IIb/IIIa antagonists (e.g., tirofiban), or erythropoietin stimulating agents. 3. The member has history of arterial or venous thrombosis.
UM ONC_1333	Erleada (apalutamide)	Positive change	Remove inclusion criteria: 2. Prostate Cancer NOTE: The preferred agent, per NCH Policies, for NON-metastatic castration-resistant prostate cancer is ENZALUTAMIDE or ABIRATERONE.
UM ONC_1333	Erleada (apalutamide)	Negative change	Add exclusion criteria: 1. Erleada (apalutamide) is being used after disease progression with the same regimen or another Androgen Receptor Inhibitor (e.g. enzalutamide or darolutamide).

UM ONC_1134	Herceptin/Ogivri/Herzuma /Ontruzant/Kanjinti/Trazi mera (trastuzumab/trastuzumab-dkst/trastuzumab-pkrb/trastuzumab-dttb/trastuzumab-anns/trastuzumab-qyyp)	Negative change	<p>Add exclusion criteria: 2. Continuation of trastuzumab after disease progression on trastuzumab-based therapy in HER-2 positive esophageal, gastroesophageal, and gastric adenocarcinomas.</p> <p>4. Total Treatment duration exceeds a the maximum 52 weeks or 1 year duration limit in the adjuvant treatment of non-metastatic HER-2 positive breast cancer. The above duration does not include any necessary therapy interruption, e.g. due to breast surgery, and post-operative recovery.</p>
UM ONC_1214	Intron-A (interferon alfa-2b)	Archive	<p>Indications no longer recommended in NCCN</p> <p>Add inclusion criteria: 2. Ovarian Cancer</p> <p>NOTE: The Preferred PARP inhibitor, per NCH Policies and NCH Pathways, for maintenance therapy-either first line or after a platinum-sensitive relapse-in ovarian cancer is niraparib.NIRAPARIB</p> <p>NOTE: Per NCH Policy and NCH Pathway, the combination of Lynparza(olaparib) and Avastin(bevacizumab) for maintenance therapy of advanced ovarian cancer, is a non-preferred regimen. The preferred. regimen in the above setting in single</p>
UM ONC_1273	Lynparza (olaparib)	Negative change	

UM ONC_1273	Lynparza (olaparib)	Positive change	<p>Add inclusion criteria: 5. Prostate Cancer</p> <p>NOTE: Lynparza( olaparib) is only recommended in metastatic castration-resistant prostate cancer with germline/somatic BRCA1 or BRCA2 deleterious/suspected deleterious mutations</p> <p>The member has metastatic castration-resistant prostate Cancer AND</p> <p>a. Tumor is positive for germline or somatic BRCA 1 or 2 mutation, based on an FDA approved companion diagnostic test (e.g. FoundationOne CDx or BRACAnalysis CDx) AND</p> <p>b. Member has disease progression on or after prior treatment with Zytiga (abiraterone) and/or Xtandi (enzalutamide) AND</p> <p>c. Lynparza (olaparib) will be used in combination with an LHRH analog (e.g. leuprolide) or as a single agent after bilateral orchiectomy.</p>
UM ONC_1273	Lynparza (olaparib)	Negative change	<p>Add exclusion criteria: 1. Disease progression while taking Lynparza (olaparib) <b>or another PARP inhibitor</b> (i.e. niraparib or rucaparib).</p>
UM ONC_1343	Mulpleta (lusutrombopag)	Positive change	<p>Remove inclusion criteria: 2. Thrombocytopenia in Chronic Liver Disease-iii. Required no platelet transfusions and/or no rescue therapy for bleeding prior to the procedure.</p>

UM ONC_1343	Mulpleta (lusutrombopag)	Positive change	<p>Remove exclusion criteria:</p> <ol style="list-style-type: none"> <li>1. <del>M</del>ulpleta (lusutrombopag) is being used Use after failure with Doptelet (avatrombopag).</li> <li>2. <del>M</del>ulpleta (lusutrombopag) is being used for any of the following conditions: <ol style="list-style-type: none"> <li>a. <del>I</del>mmune thrombocytopenia</li> <li>b. <del>A</del>plastic anemia</li> <li>c. <del>H</del>ematopoietic tumor</li> <li>d. <del>M</del>yelodysplastic syndrome</li> <li>e. <del>M</del>yelofibrosis</li> <li>f. <del>H</del>istory of splenectomy/liver transplant</li> <li>g. <del>T</del>hrombotic disease</li> </ol> </li> </ol>
UM ONC_1343	Mulpleta (lusutrombopag)	Negative change	<p>Add exclusion criteria: 1. <del>U</del>se in chronic immune thrombocytopenia (Idiopathic Thrombocytopenia Purpura- ITP),</p> <p>Add inclusion criteria: 2. <del>C</del>hronic Idiopathic Thrombocytopenic Purpura (ITP)</p> <p><del>T</del>he member has a diagnosis of relapsed/refractory chronic ITP AND</p> <ol style="list-style-type: none"> <li>a. <del>T</del>he member has insufficient response (defined by failure of platelet count to increase and stay above 30,000), intolerance, or contraindications to corticosteroids, immunoglobulins (IVIG), rituximab, AND a trial of an oral Thrombopoietin Agonist e.g. eltrombopag or avatrombopag, and and a avatrombopag.</li> <li>b. <del>T</del>he member has a platelet count <math>\leq 30,000/mm^3</math>.</li> <li>3. b. The recommended dosing guidelines for Nplate need to be followed, e.g. a starting dose of 1 mcg/kg, and subsequent increments by 1 mcg/kg, if the platelet count remains below 50,000 on the previous lower dose.</li> </ol>
UM ONC_1243	Nplate (romiplostim)	Negative change	

UM ONC_1243	Nplate (romiplostim)	Positive change	<p>Remove inclusion criteria: ITP</p> <ul style="list-style-type: none"> <li>-chronic ITP of more than 6 months duration</li> <li>- The member has insufficient response to prior splenectomy OR</li> <li>- The member has insufficient response, intolerance, or contraindications to corticosteroids, immunoglobulins (IVIG), AND Promacta (eltrombopag)</li> </ul>
UM ONC_1243	Nplate (romiplostim)	Positive change	<p>Remove exclusion criteria:</p> <ol style="list-style-type: none"> <li>1. Nplate (romiplostim) is not used to normalize platelet counts.</li> <li>2. The member has insufficient response after 4 weeks of therapy OR with appropriate dosage adjustment. Response is defined as a platelet count between 50,000/mm<sup>3</sup> and 400,000/mm<sup>3</sup>.</li> <li>3. A platelet count &gt; 400,000/mm<sup>3</sup>; therapy should be discontinued.</li> <li>4. Concurrent use with Doptelet (avatrombopag).</li> <li>5. Member has thrombocytopenia due to myelodysplastic syndrome (MDS), chemotherapy, or any cause of thrombocytopenia other than chronic ITP.</li> </ol>
UM ONC_1363	Nubeqa (darolutamide)	Positive change	<p>Remove inclusion criteria: 2. Prostate Cancer</p> <p>a. NOTE: For NON-metastatic castration-resistant prostate cancer, the preferred agents are Enzalutamide and Apalutamide over Darolutamide.</p>
UM ONC_1363	Nubeqa (darolutamide)	Positive change	<p>Add inclusion criteria: ii. Nubeqa (darolutamide) will be used in combination with LHRH analog (ADT- Androgen Deprivation Therapy).</p>



UM ONC_1363	Nubeqa (darolutamide)	Positive change	Remove exclusion criteria: 1. Lack of documented intolerance to/contraindication to Enzalutamide and Apalutamide .
UM ONC_1363	Nubeqa (darolutamide)	Negative change	Add exclusion criteria: 3. Concurrent use with other antiandrogens or CYP17 inhibitors (i.e. Abiraterone).
UM ONC_1274	Opdivo (nivolumab)	Positive change	Add inclusion criteria: 11. Esophageal Squamous Cell Carcinoma a. The member has advanced, recurrent, or metastatic esophageal squamous cell carcinoma AND b. Has experienced disease progression on or after prior fluoropyrimidine based chemotherapy (e.g. fluorouracil or capecitabine), platinum-based chemotherapy (e.g. cisplatin, carboplatin, or oxaliplatin) AND taxane monotherapy (e.g. docetaxel or paclitaxel) AND a. Opdivo (nivolumab) will be used as a single agent as third line therapy, regardless of PD-L1 status.
UM ONC_1274	Opdivo (nivolumab)	Negative change	Add inclusion criteria: 3. Non-Small Cell Lung Cancer (NSCLC) 3. NOTE: Per NCH Policy & NCH Pathways, the combination of Opdivo (nivolumab) + Yervoy (ipilimumab), with or without chemotherapy, for first line therapy of metastatic Non Small Cell Lung Cancer is a Non-Preferred regimen. Please refer to the NCH Pathway document for the recommended regimens in the above setting.

UM ONC_1274	Opdivo (nivolumab)	Negative change	<p>Add inclusion criteria: 8. Colorectal Cancer</p> <p>c. Patient has not had disease progression on prior therapy with another checkpoint inhibitor, e.g. Keytruda (pembrolizumab)</p>
UM ONC_1216	Perjeta (pertuzumab)	Negative change	<p>Add exclusion criteria: 2. The total treatment duration, in the non-metastatic setting, treatment exceeds at the maximum of 52 weeks or 1 year. The above duration does not include necessary therapy interruptions, e.g due to surgery, and/or post-operative recovery.</p>
UM ONC_1239	Pomalyst (pomalidomide)	Negative change	<p>Add inclusion criteria: a. Pomalyst (pomalidomide) may be used as follows:</p> <p>b. The member has relapsed or refractory multiple myeloma that has <b>failed 2 prior therapies for myeloma including one proteasome inhibitor &amp; one immunomodulatory agent</b></p>
UM ONC_1239	Pomalyst (pomalidomide)	Positive change	<p>Add inclusion criteria: MM- Pomalyst (pomalidomide) is being used in combination with dexamethasone</p> <p>3. AIDS-related Kaposi sarcoma</p> <p>The member has AIDS-related Kaposi sarcoma that has relapsed or is refractory to first line systemic therapy, including Doxil (liposomal doxorubicin) AND</p> <p>a. Pomalyst (pomalidomide) will be used as subsequent therapy in combination with antiretroviral therapy (ART).</p>

UM ONC_1244	Promacta (eltrombopag)	Negative change	<p>Add inclusion criteria: 2. Chronic Idiopathic Thrombocytopenic Purpura (ITP)</p> <p>The member has a diagnosis of relapsed/refractory chronic ITP, with an insufficient response to previous therapy including to corticosteroids, immunoglobulins (IVIG), rituximab, AND avatrombopag OR</p> <p>baseline platelet count of <math>\leq 30,000</math>.</p>
UM ONC_1244	Promacta (eltrombopag)	Positive change	<p>Remove inclusion criteria: 2. Chronic Idiopathic Thrombocytopenic Purpura (ITP)</p> <p>a. The member has a diagnosis of relapsed/refractory chronic ITP of more than 6 months duration AND</p> <p>b. The member is at increased risk of bleeding and has a clear downward trend in platelet count after the last treatment AND</p> <p>c. Platelet count is less than <math>30,000/mm^3</math> (levels are obtained within the last 4 weeks) AND</p> <p>d. The member has insufficient response to prior splenectomy OR</p> <p>e. The member has insufficient response, intolerance, or contraindications to corticosteroids and immunoglobulins (IVIG) AND</p> <p>f. Insufficient response to prior therapy is defined as a platelet count <math>&lt; 50,000/mm^3</math>.</p>
UM ONC_1244	Promacta (eltrombopag)	Positive change	<p>Remove exclusion criteria:</p> <p>1. Promacta (eltrombopag) is not used to normalize platelet counts.</p> <p>1. The member has insufficient response after 4 weeks of therapy OR with appropriate dosage adjustment. Response is defined as a platelet count between <math>50,000/mm^3</math> and <math>400,000/mm^3</math>.</p> <p>2. A platelet count <math>&gt; 400,000/mm^3</math>, therapy should be discontinued.</p> <p>3. Concurrent use with other TPO receptor agonist such as Nplate (romiplostim) or <b>Doptelet (avatrombopag)</b>.</p>

UM ONC_1315	Rydapt (midostaurin)	Negative change	<p>Add inclusion criteria: 2. Acute Myelogenous Leukemia (AML) The member has documented FLT3 mutation-positive AML ( ITD and/or TKD mutations) AML as detected by an FDA approved test e.g. , the LeukoStrat CDx FLT3 Mutation Assay</p>
UM ONC_1315	Rydapt (midostaurin)	Positive change	<p>Remove inclusion criteria: AML - iii. For relapsed/refractory disease as a component of repeating the initial successful induction regimen if late relapse (≥12 months).</p>
UM ONC_1315	Rydapt (midostaurin)	Negative change	<p>Add exclusion criteria: Disease progression on Rydapt(misostaurin) or another FLT-3 inhibitor, e.g. giltertinib</p>
UM ONC_1315	Rydapt (midostaurin)	Positive change	<p>Remove exclusion criteria: 2. Member has AML related to prior chemotherapy or RT for another cancer. 3. Prior use of cytotoxic therapy including azacitidine or decitabine.</p>
UM ONC_1043	Tarceva (Erlotinib)	Negative change	<p>Add inclusion criteria: 2. Non-Small Cell Lung Cancer (NSCLC) - NOTE: Tarceva(erlotinib) + bevacizumab is a Non-Preferred regimen per NCH Policy &amp; NCH Pathway. b. Tarceva(erlotinib) may be used as a single agent forThe member has recurrent/metastatic, EGFR mutation positive NSCLC if <b>the patient has an intolerance/contraindication to Tagrisso(osimertinib).</b></p>

UM ONC_1043	Tarceva (Erlotinib)	Positive change	Remove exclusion criteria: 2. Tarceva (Erlotinib) is being used concurrently with other (except for pancreas cancer indications).
UM ONC_1199	Tasigna (nilotinib)	Negative change	<p>Add inclusion criteria: 1.2. Chronic Myeloid Leukemia (CML)</p> <p>NOTE: Per NCH Policy &amp; NCH Pathway, generic imatinib is the preferred agent for first line therapy of BCR-ABL positive Chronic Myeloid Leukemia. Second generation Tyrosine Kinase Inhibitors, such as Tasigna (nilotinib), may be used if there is documented intolerance to generic imatinib OR documented disease progression on generic imatinib.</p> <p>a. The member has newly diagnosed CML (Philadelphia chromosome or BCR-ABL1 positive) AND</p> <p>b. Tasigna (nilotinib) may be used as a single agent as ANY of the following:</p> <p>i. Primary/initial therapy in members who are intolerant or have a contraindication to Gleevec (imatinib) OR</p> <p>ii. Subsequent therapy in members who have suboptimal response or relapse after initial response to a Tyrosine Kinase Inhibitor (e.g. imatinib).</p>

UM ONC_1199	Tasigna (nilotinib)	Positive change	<p>Remove inclusion criteria:</p> <p>CML</p> <ul style="list-style-type: none"> <li>a. Primary treatment for members with newly diagnosed CML (Ph+ or BCR-ABL 1 positive) OR</li> <li>b. Follow-up therapy, after Tasigna (nilotinib), Gleevec (imatinib) or Sprycel (dasatinib) primary treatment OR</li> <li>c. Treatment of members with advanced phase CML <ul style="list-style-type: none"> <li>i. As a single agent for accelerated phase</li> <li>ii. As a single agent or in combination with induction chemotherapy followed by hematopoietic stem cell transplant for blast crisis OR</li> </ul> </li> <li>d. Post-transplant follow-up treatment in members with <ul style="list-style-type: none"> <li>i. Molecular relapse (polymerase chain reaction positive) following complete cytogenetic remission</li> <li>ii. Cytogenetic relapse or those who are not in cytogenetic remission.</li> </ul> </li> <li>e. As follow up therapy in members with a F317L/V/I/C, T315A, or V299L</li> </ul>
UM ONC_1199	Tasigna (nilotinib)	Positive change	<p>Remove exclusion criteria:</p> <ul style="list-style-type: none"> <li>2. Changing to Tasigna (nilotinib) in GIST with no failure or intolerance to Sutent (sunitinib), Gleevec (imatinib), or Stivarga (regorafenib).</li> </ul>
UM ONC_1199	Tasigna (nilotinib)	Negative change	<p>Add exclusion criteria: 4. Dosing exceeds single dose limit of Tasigna (nilotinib) 180 (50 mg), 60 (150 mg), 60 (200 mg) capsules per month.</p>

Add inclusion criteria: 3. Follicular Lymphoma

a. The member has relapsed or refractory follicular lymphoma and transformation to a higher grade lymphoma (e.g. Diffuse Large B-cell Lymphoma) has been ruled out by biopsy AND

b. Tazverik (tazemetostat) will be used as a single agent when the following criteria are met:

i. Member has no satisfactory alternative treatment options, specifically, the patient has failed CVP/CHOP, bendamustine + rituximab, single agent rituximab, lenalidomide + rituximab, and the patient is not a candidate for hematopoietic cell transplant ( autologous or allogeneic) OR

ii. The member has tumors positive for EZH2 mutation as detected by an FDA-approved test (e.g. the cobas EZH2 Mutation Test) AND has experienced disease progression on at least 2 prior therapies

UM ONC\_1385 Tazverik™ (tazemetostat) Positive change

Remove inclusion criteria: 4. Small Cell Lung Cancer (SCLC)

a. The member has extensive stage SCLC AND

b. Tecentriq (atezolizumab) is being used may be used as initial treatment in combination with etoposide and carboplatin or cisplatin followed by atezolizumab maintenance in members who have had a complete response/partial response/stable disease after completion of [atezolizumab + etoposide + carboplatin/cisplatin].

UM ONC\_1299 Tecentriq (atezolizumab) Positive change

UM ONC_1299	Tecentriq (atezolizumab)	Negative change	<p>Add inclusion criteria: 4. Small Cell Lung Cancer (SCLC) The above regimen may also be used in the second/subsequent line setting if the member has not received prior therapy with a checkpoint inhibitor, e.g. Keytruda</p> <p>5. Breast Cancer - members who have not received prior therapy with a checkpoint inhibitor, e.g. Keytruda.</p>
UM ONC_1299	Tecentriq (atezolizumab)	Positive change	<p>Add inclusion criteria: 6. Hepatocellular Carcinoma In members with unresectable or metastatic hepatocellular carcinoma AND preserved liver function ( Child-Pugh Class A), who have not received prior therapy with a checkpoint inhibitor, e.g. Keytruda. Tecentriq (atezolizumab) may be used in combination with bevacizumab as first line therapy in the metastatic setting.</p>
UM ONC_1340	Tibsovo(ivosidenib)	Positive change	<p>Remove inclusion criteria: AML</p> <p>i. In members ≥ 60 years for</p> <p>a. Treatment induction when not a candidate for intensive remission induction therapy or declines intensive therapy OR</p> <p>b. Post-remission therapy following response to previous lower intensity therapy OR</p> <p>ii. For relapsed/refractory disease as a component of repeating the initial successful induction regimen if late relapse (≥12 months) or as a single agent.</p>
UM ONC_1340	Tibsovo(ivosidenib)	Positive change	<p>Add inclusion criteria: AML for documented IDH1 gene-mutation as detected by an FDA approved test, e.g. <b>Abbott</b> RealTime IDH1 Assay AND</p> <p>b. Tibsovo (ivosidenib) may be used as a single agent as ANY of the following:</p> <p>i. Induction/initial treatment,</p> <p>ii. Post-remission/consolidation therapy following response to induction/initial treatment</p> <p>iii. For relapsed/refractory AML</p>



UM ONC_1340	Tibsovo(ivosidenib)	Positive change	<p>Remove exclusion criteria:</p> <p>1. <del>Concurrent use with other anticancer therapy or radiotherapy.</del></p> <p>Add inclusion criteria: <del>Acute Promyelocytic Leukemia (APL)</del>  Trisenox (arsenic trioxide) may be used for the treatment of Acute Promyelocytic Leukemia (APL) -regardless of the APL Risk Category- as induction and/or consolidation therapy, 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).</p>
UM ONC_1069	Trisenox (Arsenic Trioxide)	Positive change	

1. APL

a. Member has a diagnosis of acute promyelocytic leukemia (APL) characterized by the presence of the t(15;17) translocation or PML/RAR-alpha gene expression AND

b. Trisenox (arsenic trioxide) is being used in ONE of the following:

i. Members with high risk disease (WBC > 10,000):

1. In combination with all-trans-retinoic acid (ATRA) AND idarubicin or daunorubicin, or ATRA and gemtuzumab as induction OR

2. In combination with ATRA, gemtuzumab, or ATRA and idarubicin or daunorubicin as consolidation therapy in members with no cardiac issues.

OR

ii. Members with low/intermediate-risk disease (WBC ≤ 10,000):

1. In combination with all-trans-retinoic acid as induction or consolidation therapy OR

OR

iii. Members with relapsed disease:

1. As initial therapy for the following:

i. In members with no prior exposure to arsenic trioxide or with late relapse (≥6 months) after receiving an arsenic trioxide-containing regimen

ii. In combination with tretinoin and idarubicin for members with early relapse (<6 months) after receiving only tretinoin or arsenic trioxide (no anthracycline)

iii. For members with early relapse (<6 months) after receiving an arsenic trioxide/anthracycline-containing regimen

OR

2. As consolidation therapy for up to 6 cycles in nontransplant candidates achieving second remission.

UM ONC\_1069 Trisenox (Arsenic Trioxide) Positive change

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Remove inclusion criteria: 2. Breast Carcinoma

a. NOTE: Tukysa (tucatinib) is a non-preferred drug per NCH Policy and NCH Pathway. The preferred anti-HER2 tyrosine kinase inhibitor is LAPATINIB.

ii. If member received prior lapatinib therapy, the latter therapy was completed ≥ 12 months prior to starting tucatinib AND

UM ONC\_1401 Tukysa (tucatinib) Positive change

iii. Member has experienced disease progression on prior therapy with

[trastuzumab + pertuzumab] and prior therapy with trastuzumab emtansine AND

UM ONC_1401	Tukysa (tucatinib)	Positive change	Add inclusion criteria: The member has experienced disease progression on prior therapy with Trastuzumab + Pertuzumab + Taxane AND Kadcylla (trastuzumab emtansine) in the metastatic setting .
UM ONC_1070	Valstar (Valrubicin)	Positive change	Remove inclusion criteria: 2. Non- muscle invasive Bladder Cancer ( Tis- Carcinoma In Situ) a. The member has recurrent or persistent carcinoma non-muscle invasive carcinoma of the bladder- Tis or Carcinoma In Situ- <b>that is refractory to local ( intravesical) therapy with BCG</b>
UM ONC_1070	Valstar (Valrubicin)	Positive change	Remove inclusion criteria: In situ of the urinary bladder (Cis) AND The member has failed the following i. Mitomycin AND ii. Gemcitabine AND c. The member is not a candidate for immediate cystectomy.
UM ONC_1365	Xpovio (selinexor)	Positive change	Add inclusion criteria: 2. Multiple Myeloma- b. Selinexor is being used as a single agent 3. Diffuse Large B-cell Lymphoma (DLBCL ) Member has relapsed or refractory diffuse large B-cell Lymphoma, that has progressed on 2 or more prior therapies AND Xpovio (selinexor) will be used as a single
UM ONC_1365	Xpovio (selinexor)	Positive change	Remove inclusion criteria: 2. Multiple Myeloma- b. Selinexor use in combination with dexamethasone

UM ONC_1228	Xtandi (enzalutamide)	Negative change	Add inclusion criteria: if the member has a contraindication or intolerance to Nubeqa (darolutamide).
new drug policy	Zepzelca (lurbinectedin)	n/a	n/a