

Policy #	Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
New	Empaveli (pegcetacoplan)	N/A	N/A	N/A
New	Lumakras (sotorasib)	N/A	N/A	N/A
New	Truseltiq (infigratinib)	N/A	N/A	N/A
New	Rybrevant (amivantamab-vmjw)	N/A	N/A	N/A
UM ONC_1028	Avastin (bevacizumab)/Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr)	Negative change	Add inclusion criteria: Colorectal cancer II. As subsequent therapy after progression on a prior non-bevacizumab based regimen given in combination with FOLFOX, FOLFIRI, XELIRI, and XELOX/CapeOX. iii.Bevacizumab may be used in a maximum of 2 lines of therapy, in the metastatic setting.	Per FDA labeling
UM ONC_1028	Avastin (bevacizumab)/Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr)	Positive change	Remove exclusion criteria: 1.Off-label indications for Avastin (bevacizumab)/Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr) in breast, ovarian, soft tissue sarcoma, and endometrial cancers shall be reviewed for appropriateness per National Comprehensive Cancer Network (NCCN) compendium or other CMS-approved compendia, American Society of Clinical Oncology (ASCO) clinical guidelines, or other compelling medical literature publications.	Per Compendia Listing
UM ONC_1043	Tarceva (Erlotinib)	Positive change	Remove exclusion criteria: 1. Off-label indications for Tarceva (Erlotinib) in pancreatic and kidney cancers shall be reviewed for appropriateness per National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or other compelling medical literature publications.	Per Compendia Listing
UM ONC_1069	Trisenox (Arsenic Trioxide)	No Clinical Changes	N/A	N/A
UM ONC_1070	Valstar (Valrubicin)	Negative change	Add inclusion criteria: a. The member has recurrent or persistent non-muscle invasive carcinoma of the bladder, Tis or Carcinoma In Situ, that is refractory 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 Clinical Trial Analysis/Criteria
UM ONC_1138	Erythropoiesis Stimulating Agents (ESA)	Positive change	Add inclusion criteria: 6. Retacrit (epoetin alfa-epbx) and Procrit/Epogen (epoetin alfa) are the PREFERRED medications whenever Aranesp (darbepoetin alfa) is requested	More Cost Effective Alternative(s)
UM ONC_1199	Tasigna (nilotinib)	Positive change	Add inclusion criteria: Add indications for Ph+ B-cell ALL i.Primary/initial therapy in members who are intolerant or have a contraindication to Gleevec (imatinib) OR ii.Subsequent therapy in members who have suboptimal response or relapse after initial response to a Tyrosine Kinase Inhibitor [e.g. Gleevec (imatinib)]. iii.For Ph+ B-cell ALL, Tasigna may be used with or without chemotherapy for the above indications and for maintenance therapy.	Per FDA labeling
UM ONC_1199	Tasigna (nilotinib)	Negative change	Add exclusion criteria: Nilotinib is contraindicated for use in members with the following mutations of BCR-ABL1: T315I, Y253H, E255K/V, F359V/C/I or G250E	Per Compendia Listing
UM ONC_1261	Cyramza (ramucirumab)	No Clinical Changes	N/A	N/A

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UM ONC_1313	Alunbrig (brigatinib)	Negative change	<p>Add inclusion criteria: NOTE: The preferred targeted therapies, per NCH policy and pathway, for recurrent, advanced, or metastatic ALK+ NSCLC are as follows: i. First-line therapy: Alecensa (alectinib) ii. Subsequent-line therapy: Xalkori (crizotinib)-Lorbrena (lorlatinib) or Alunbrig (brigatinib) (if failed crizotinib). a. 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: i. First line or subsequent therapy if there is intolerance or contraindication to Alecensa (alectinib), OR ii. Second line/subsequent therapy if there has been disease progression on prior Xalkori (crizotinib) therapy.</p>	Per Clinical Trial Analysis/Criteria
UM ONC_1315	Alunbrig (brigatinib)	Negative change	<p>Add exclusion criteria: 4. Treatment exceeds the maximum limit of 180 (30 mg) tablets/month, or 60 (90 mg), or 30 (180 mg) tablets/month.</p>	Per FDA labeling
UM ONC_1315	Rydapt (midostaurin)	Negative change	<p>Add exclusion criteria: 3. Lack of documented FLT3 mutation on leukemia cells (applies to AML)</p>	Per FDA labeling
UM ONC_1340	Tibsovo (ivosidenib)	No Clinical Changes	N/A	N/A
UM ONC_1385	Tazverik (tazemetostat)	Positive change	<p>Remove inclusion criteria: Follicular Lymphoma 3. NOTE: Tazverik (tazemetostat) is a non-preferred agent per NCH Policy & NCH Pathway. The member's lymphoma AND has experienced disease progression on at least 2 prior therapies</p>	Per NCH L1 Pathway
UM ONC_1386	Tazverik (tazemetostat)	Positive change	<p>Add inclusion criteria: Follicular Lymphoma a. The member has relapsed or refractory follicular lymphoma positive for EZH2 mutation as detected by an FDA-approved test (e.g. the cobas EZH2 Mutation Test), and the member has experienced disease progression on 2 prior lines of therapy (e.g., single agent rituximab, bendamustine+rituximab)</p>	Per Clinical Trial Analysis/Criteria
UM ONC_1385	Tazverik (tazemetostat)	Positive change	<p>Remove exclusion criteria: 3. Lack of documentation of INI1-deficient tumor by immunohistochemistry (applies to epithelioid sarcoma only)</p>	Per Clinical Trial Analysis/Criteria
UM ONC_1401	Tukysa (tucatinib)	Positive change	<p>Add inclusion criteria: a. Tukysa (tucatinib) may be used in members with recurrent unresectable or metastatic HER-2 positive breast cancer, if there is an intolerance/contraindication to lapatinib use.</p>	Per FDA labeling
UM ONC_1408	Zepzelca (lurbinectedin)	Negative change	<p>Add inclusion criteria: 2. Small Cell Lung Cancer (SCLC) NOTE: Zepzelca (lurbinectedin) is a non-preferred agent per NCH Policy and NCH Pathway. Rationale: FDA approval was based on a phase II basket trial. The primary endpoints of the trial were Overall Response Rate and Response Duration. There is no information on disease free survival or overall survival. NOTE: Rate of febrile neutropenia was 5% so primary prophylaxis for febrile neutropenia with MGF is not supported/recommended.</p>	Per Clinical Trial Analysis/Criteria
UM ONC_1408	Zepzelca (lurbinectedin)	Negative change	<p>Add exclusion criteria: 3. Any neuro-endocrine carcinoma that is of Non-Lung (non-pulmonary) origin, for example poorly differentiated neuroendocrine carcinoma of GI, GU, Head and Neck, and metastatic poorly differentiated neuroendocrine carcinoma of an Unknown Primary Origin. This exclusion is based on the lack of clinical trial evidence supporting the use of lurbinectedin in the above settings.</p>	Per FDA labeling