| Policy # | Policy Name | Type of Change | Brief Description of Policy Change | Reason for Changes |
|---|---|---|---|---|
| NEW | Carvykti (ciltacabtagene autoleucel) | N/A | N/A | N/A |
| NEW | Vonjo (pacritinib) | N/A | N/A | N/A |
| UM ONC_1043 | Tarceva (Erlotinib) | Negative change | Add inclusion criteria:<br>B.Non-Small Cell Lung Cancer (NSCLC)<br>1.NOTE: Per NCH Pathway & NCH Policy, [Tarceva (erlotinib) + Cyramza (ramucirumab)] and [Tarceva (erlotinib) + Avastin (bevacizumab)/bevacizumab biosimilar products] are Non-Prefered regimens for the treatment of NSCLC The preferred agent for first line therapy of recurrent/metastatic, EGFR mutation positive( exon 19 deletion or L858R) Non-Small Cell Lung Cancer is Tagrisso (osimertinib) based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) to support that single agent Tarceva (erlotinib) or Tarceva (erlotinib) containing regimen is superior to Tagrisso (osimertinib).1 Please see UM ONC_1287 Tagrisso™ (osimertinib) policy. | Per NCH Pathway exclusion |
| UM ONC_1043 | Tarceva (Erlotinib) | Positive change | Add inclusion criteria:<br>Pancreatic Cancer<br>1.Tarceva (erlotinib) may be used in combination with Gemzar (gemcitabine) in members with advanced, unresectable, or metastatic pancreatic cancer as initial or subsequent therapy. | Per FDA labeling |
| UM ONC_1043 | Tarceva (Erlotinib) | Negative change | Add exclusion criteria:<br>A.Disease progression while taking Tarceva (erlotinib). | Per Clinical Trial Analysis/Criteria |
| UM ONC_1043 | Tarceva (Erlotinib) | Positive change | Remove inclusion criteria:<br>A.B.Tarceva (Erlotinib) is being used concurrently ~~with other tyrosine kinase inhibitors such as Iressa (Gefitinib), Gleevec (Imatinib), Sprycel (Dasatinib), Tasigna (Nilotinib), Tykerb (Lapatinib), Sutent (Sunitinib), Nexavar (Sorafenib), Votrient (Pazopanib), or~~ with chemotherapy. | Per Clinical Trial Analysis/Criteria |
| UM ONC_1089 | Libtayo (cemiplimab-rwlc) | Positive change | Remove inclusion criteria:<br>B.Cutaneous Squamous Cell Carcinoma (CSCC)<br>1.NOTE: Per NCH Policy Libtayo (cemiplimab-rwlc) is the preferred agent for use in metastatic cutaneous squamous cell carcinoma, over Keytruda (pembrolizumab).<br>D.Non-Small Cell Lung Cancer<br>1.NOTE 1: For recurrent/metastatic, NSCLC, with PD-L1 ≥ 50%, the recommended Immune Checkpoint Inhibitor per NCH Policy and NCH Pathway is Keytruda (pembrolizumab). This recommendation is based on the results of the KEYNOTE-024 trial, including the 5-year long term update of the latter trial, both referenced below. Furthermore there is no Level 1 evidence (randomized trial and/or meta-analysis) to support that Libtayo (cemiplimab) therapy results in superior outcomes compared to Keytruda (pembrolizumab) therapy in the above sub-group of patients with NSCLC. | Per Compendia Listing |
| UM ONC_1089 | Libtayo (cemiplimab-rwlc) | Negative change | Add inclusion criteria:<br>1.Libtayo (cemiplimab) may be used as monotherapy in members with locally advanced, recurrent/metastatic NSCLC, with PD-L1 ≥ 50%, negative for the following actionable molecular markers (e.g., ALK, EGFR, and ROS-1)<br>Libtayo (cemiplimab) use is not supported if the member has experienced disease progression on prior Immune Checkpoint Inhibitor therapy, for metastatic Non Small Cell Lung Cancer including ~~Imfinzi (durvalumab),~~ Keytruda (pembrolizumab), Opdivo (nivolumab), OR Tecentriq (atezolizumab). | Per Clinical Trial Analysis/Criteria |
| UM ONC_1133 | Erbitux (Cetuximab) | Positive change | Remove inclusion criteria:<br>B.Head and Neck Cancers<br>1.NOTE: Randomized data have shown that Erbitux (cetuximab) + radiation therapy is inferior to cisplatin + radiation therapy. Therefore, the use of Erbitux (cetuximab) + radiation therapy for curative intent is only recommended for members who have a contraindication and/or intolerance to cisplatin use.<br>1.The member has ~~non-nasopharyngeal~~ squamous cell carcinoma of the head and neck Erbitux (cetuximab) may be used in ANY of the following situations.<br>a.As a part of primary/definitive/curative-intent concurrent chemoradiation (Erbitux + Radiation) as a single agent f or locally advanced disease ~~for members with a contraindication and/or intolerance to cisplatin use~~ OR<br>b.For locally advanced/recurrent/metastatic disease as a single agent, or in combination with chemotherapy.<br>C.Colorectal Cancer<br>2.NOTE: Erbitux (cetuximab) + Braftovi (encorafenib) is NCH preferred L1 pathway for second-line or subsequent therapy in the metastatic setting, for BRAFV600E positive colorectal cancer. | Per NCH Pathway expansion |

| | | | | |
|---|---|---|---|---|
| UM ONC_1133 | Erbitux (Cetuximab) | Negative change | Add inclusion criteria:<br>B.Head and Neck Cancers<br>2.NOTE: Per NCH Pathway & NCH Policy,[Erbitux (cetuximab) + Taxotere (docetaxel)] or [Erbitux (cetuximab) + Keytruda (pembrolizumab)] are Non-Preferred regimens for the treatment of advanced/metastatic head and neck 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. When clinically appropriate, please refer to NCH Pathway for the preferred treatments recommended for use in advanced/metastatic head and neck cancers. | Per NCH Pathway exclusion |
| UM ONC_1133 | Erbitux (Cetuximab) | Positive change | Add inclusion criteria:<br>C.Colorectal Cancer<br>1.The member has stage IV, KRAS/NRAS Wild-Type metastatic colorectal cancer and Erbitux (cetuximab) is being used as a single agent or in combination with FOLFIRI, FOLFOX, FOLFIRINOX,or irinotecan in the initial or subsequent line setting, except for members who have experienced disease progression on prior therapy with Erbitux (cetuximab) or Vectibix (panitumumab). | Per Compendia Listing |
| UM ONC_1133 | Erbitux (Cetuximab) | Negative change | Add exclusion criteria:<br>B.Pre /Post-operative chemotherapy for potentially resectable liver metastases from KRAS/NRAS wild-type colorectal cancer. | Per Compendia Listing |
| UM ONC_1179 | Abraxane (nab-paclitaxel) | Positive change | Remove inclusion criteria:<br>NOTE: For all cancer types in which a taxane (Taxol, Taxotere, Abraxane) is indicated-except pancreas adenocarcinoma- NCH Policy & NCH Pathway require the use of solvent-based Taxol (paclitaxel) or Taxotere (docetaxel) over the use of Abraxane (nab-paclitaxel), unless there is a history of a severe allergic reaction/anaphylaxis to solvent-based Taxol (paclitaxel) or Taxotere (docetaxel).<br>B. ~~Metastatic Triple Negative~~ Breast Cancer:<br>The combination of Abraxane (nab paclitaxel) + Tecentriq (atezolizumab) is NOT recommended per NCH Policy and per NCH Pathway because of the voluntary withdrawal by the manufacturer of Tecentriq (atezolizumab), from the FDA, of the above indication.<br>Single agent Abraxane (nab paclitaxel) is non-preferred per NCH Policy and NCH Pathway for metastatic breast cancer regardless of phenotype.<br>D.Non-Small Cell Lung Cancer (NSCLC)<br>1.In the first line setting for metastatic, squamous, Non-Small Cell Lung Cancer, Taxol (paclitaxel) is preferred over Abraxane (nab-paclitaxel). The above recommendation is based on results of KEYNOTE-407 trial which showed no difference in outcomes between the use of Taxol (paclitaxel) and Abraxane (nab-paclitaxel).<br>2.For first & subsequent line settings, for both metastatic and non-metastatic Non-Small Cell Lung Cancer, the use of solvent based Taxol (paclitaxel) or Taxotere (docetaxel) is preferred over Abraxane (nab-paclitaxel) unless there is a history of a severe allergic reaction/anaphylaxis to solvent-based Taxol (paclitaxel) or Taxotere (docetaxel). This recommendation is based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) to show superior outcomes with Abraxane (nab-paclitaxel) compared to Taxol (paclitaxel) or Taxotere (docetaxel). | Per NCH Pathway exclusion |

| | | | | |
|---|---|---|---|---|
| UM ONC_1179 | Abraxane (nab-paclitaxel) | Negative change | Add inclusion criteria:<br>A. Breast Cancer:<br>1.NOTE: Per NCH Pathway & NCH Policy, Abraxane (nab-paclitaxel) is a non-preferred drug for the treatment of recurrent unresectable or metastatic breast cancer. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes compared to Taxol (paclitaxel) or Taxotere (docetaxel) therapies. Please refer to NCH Pathway for the preferred therapies recommended for use in the treatment of breast cancer.<br>B.Pancreatic Adenocarcinoma<br>1.Abraxane (nab-paclitaxel) may be used in combination with gemcitabine for as neoadjuvant therapy for borderline resectable or locally advanced disease OR<br>2.Abraxane (nab-paclitaxel) may be used in combination with gemcitabine for first or subsequent line therapy for recurrent/metastatic disease ~~(~~for members who have not received/progressed on prior Abraxane (nab-paclitaxel)] ~~the above regimen for metastatic disease).~~<br>C.Non-Small Cell Lung Cancer (NSCLC)<br>3.NOTE: Per NCH Pathway & NCH Policy, Abraxane (albumin-bound paclitaxel) +/- carboplatin +/- pembrolizumab (for squamous histology)/atezolizumab (for nonsquamous histology) are Non-Preferred regimens for initial or subsequent treatment of NSCLC. The use of solvent based Taxol (paclitaxel) or Taxotere (docetaxel) is preferred over Abraxane (nab-paclitaxel) unless there is a history of a severe allergic reaction/anaphylaxis to solvent-based Taxol (paclitaxel) or Taxotere (docetaxel). This recommendation is based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) to show superior outcomes with Abraxane (nab-paclitaxel) compared to Taxol (paclitaxel) or Taxotere (docetaxel).<br>G.Non-Small Cell Lung Cancer<br>1.NOTE: The combination of [Yervoy (ipilimumab + Opdivo (nivolumab)], [Opdivo (nivolumab + Yervoy (ipilimumab) + Alimta (pemetrexed) + carboplatin/cisplatin ], or Opdivo (nivolumab + Yervoy (ipilimumab) +Taxol (paclitaxel) + carboplatin/cisplatin] are Non-Preferred regimens for the treatment of metastatic Non-Small Cell Lung Cancer~~, in the first-line/subsequent line setting, is Non-Preferred per NCH Policy and NCH Pathway.~~ | Per NCH Pathway exclusion |
| UM ONC_1201 | Yervoy (ipilimumab) | Negative change | Add inclusion criteria:<br>C.Melanoma<br>1.NOTE 1: The preferred drugs, per NCH Policies & NCH Pathway, for the adjuvant therapy of completely resected stage III melanoma are Opdivo (nivolumab) OR Keytruda (pembrolizumab). Please refer to UM ONC_1274 Opdivo (nivolumab) policy or UM ONC_1263 Keytruda (pembrolizumab) policy. Adjuvant Yervoy (ipilimumab) + Opdivo (nivolumab) is not recommended in this setting. This recommendation is based on randomized data showing inferior outcomes with Yervoy (ipilimumab + Opdivo (nivolumab) compared to single agent Opdivo (nivolumab).<br>2.NOTE 2: Per NCH Pathway & NCH Policy, Yervoy (ipilimumab) + Keytruda (pembrolizumab) is a Non-Preferred regimen for first line treatment of unresectable or metastatic melanoma based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes compared to NCH preferred regimens [e.g., Opdivo (nivolumab) +/- Yervoy (ipilimumab)] . Please refer to NCH pathway for the preferred treatments for unresectable or metastatic melanoma.<br>iii.NOTE 3: When Opdivo (nivolumab) is used in combination with Yervoy (ipilimumab), the recommended dose of Yervoy (ipilimumab) should not exceed 1 mg/kg every 3 weeks for a maximum of 4 cycles with Opdivo (nivolumab) dosed at 3 mg/kg every 3 weeks followed by maintenance Opdivo (nivolumab).<br>E.Colorectal Cancer<br>1. NOTE: Yervoy (ipilimumab) + Opdivo (nivolumab) is not a preferred regimen per NCH Policy or& NCH Pathway for unresectable/metastatic/recurrent microsatellite instability-high (MSI-H) or mismatch repair deficient [dMMR] colorectal cancer. The preferred drug in this setting is single agent Keytruda (pembrolizumab). This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with Yervoy (ipilimumab) + Opdivo (nivolumab) over Keytruda (pembrolizumab) in the above setting.<br>F.Hepatocellular Carcinoma (HCC)<br>1.NOTE: Yervoy (ipilimumab) + Opdivo (nivolumab) is not a preferred drug regimen per NCH Policy or NCH Pathway for ~~the initial or subsequent~~ the treatment of hepatocellular carcinoma. Please refer to the NCH Pathway document for the most current recommended therapies for hepatocellular carcinoma. This recommendation is based on the lack of Level 1 evidence (randomized trial and/or meta-analyses) showing superior outcomes with Yervoy (ipilimumab) over the preferred ~~first and~~ second line therapies recommended per the NCH Pathway. | Per NCH Pathway exclusion |

| | | | | |
|---|---|---|---|---|
| UM ONC_1234 | Zevalin (ibritumomab tiuxetan) | Negative change | Remove inclusion criteria:<br>B.Non-Hodgkin's Lymphoma (NHL)<br>1.The member has CD20 positive B-cell lymphoma specifically: Follicular Lymphoma, ~~histologic transformation to Diffuse Large B-Cell Lymphoma from a Nodal Marginal Zone Lymphoma~~ OR primary cutaneous diffuse large B-cell lymphoma leg type | Per Compendia Listing |
| UM ONC_1234 | Zevalin (ibritumomab tiuxetan) | Negative change | Add inclusion criteria:<br>B.Non-Hodgkin's Lymphoma (NHL)<br>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. 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 NCH Pathway exclusion |
| UM ONC_1235 | Doxil or Lipodox (liposomal doxorubicin) | Negative change | Add inclusion criteria:<br>E.Multiple Myeloma<br>1.The member has relapsed or refractory multiple myeloma and Doxil/Lipodox (liposomal doxorubicin) will be used in combination with bortezomib (if have not previously received) +/- dexamethasone following one prior therapy. | Per FDA labeling |
| UM ONC_1235 | Doxil or Lipodox (liposomal doxorubicin) | Negative change | Add exclusion criteria:<br>B.Dosing exceeds single dose limit of Doxil/Lipodox (liposomal doxorubicin) 50 mg/m2 (for ovarian cancer), 20 mg/m2 (for KS), and 30 mg/m2 (for multiple myeloma). | Per FDA labeling |
| UM ONC_1239 | Pomalyst (pomalidomide) | Positive change | Remove inclusion criteria:<br>B.Multiple Myeloma<br>1.NOTE: The preferred immunomodulatory agent, for first line therapy of newly diagnosed myeloma, and first line therapy for myeloma in first relapse, per NCH policy and pathway, is Revlimid (lenalidomide) over Pomalyst (pomalidomide) or Thalomid (thalidomide). | Per NCH Pathway expansion |
| UM ONC_1239 | Pomalyst (pomalidomide) | Positive change | Remove inclusion criteria:<br>B.Multiple Myeloma<br>a.The member has relapsed or refractory multiple myeloma that has failed 2 prior therapies for myeloma including one proteasome inhibitor ~~preferably Revlimid (unless intolerance/contraindication & one immunomodulatory agent preferably Velcade (unless contraindication/intolerance),~~ and Pomalyst (pomalidomide) is being used as a single agent OR in combination with dexamethasone | Per NCH Pathway expansion |
| UM ONC_1239 | Pomalyst (pomalidomide) | Positive change | Add inclusion criteria:<br>B.Multiple Myeloma<br>i.In combination with dexamethasone or corticosteroid equivalent unless there is an intolerance/contraindication to a corticosteroid.<br>v. In combination with ixazomib +/- dexamethasone<br>vi.In combination with Velcade (bortezomib) +/- dexamethasone<br>iv.vii.In combination with Isatuximab-irfc +/- dexamethasone. | Per NCH Pathway expansion |
| UM ONC_1264 | Zydelig (idelalisib) | Negative change | Remove inclusion criteria:<br>B. Small Lymphocytic Lymphoma<br>C.Follicular Lymphoma, Extra-Nodal (Gastric, Lung, Eyelid, etc.) Marginal Zone Lymphoma, Splenic Marginal Zone Lymphoma and Nodal Marginal Zone Lymphoma<br>1.NOTE: Zydelig (idelalisib) is not recommended for Follicular Lymphoma/all types of Marginal Zone Lymphoma per NCH Policy or NCH Pathway because of the risk of severe toxicities outweighs the benefits. | FDA & NCCN Withdrawal |
| UM ONC_1264 | Zydelig (idelalisib) | Negative change | Add inclusion criteria:<br>B.Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma/Follicular Lymphoma<br>1.NOTE: Zydelig (idelalisib) is NOT recommended as an appropriate therapeutic agent for either CLL/SLL or Follicular Lymphoma per NCH Policy and NCH Pathway because the risk of severe toxicities outweighs the benefits. Additionally, due to an increase risk in mortality, FDA withdrew Zydelig (idelisib) indications for Follicular Lymphoma and Small Lymphocytic Leukemia on January 19, 2022. Zydelig will remain on the market for CLL, this too is not recommended per NCH Policy and NCH Pathway. | FDA & NCCN Withdrawal |

| | | | | |
|---|---|---|---|---|
| UM ONC_1274 | Opdivo (nivolumab) | Positive change | Add inclusion criteria:<br>B.Melanoma<br>1.Opdivo (nivolumab) may be used in members with stage III or metastatic/recurrent melanoma as follows:<br>a.As a single agent for adjuvant therapy of high-risk Stage III melanoma following complete resection of the primary tumor with or without a complete regional lymph node dissection. Maximum duration of therapy is one year. NOTE: ~~Either Keytruda (pembrolizumab) or Opdivo (nivolumab) may be used in the above setting per NCH Policy.~~ Adjuvant Yervoy (ipilimumab) + Opdivo (nivolumab) is not recommended in this setting. This recommendation is based on randomized data showing inferior outcomes with Yervoy (ipilimumab + Opdivo (nivolumab) compared to single agent Opdivo (nivolumab).<br>C.Non-Small Cell Lung Cancer (NSCLC)<br>2.Opdivo (nivolumab) may be used as neoadjuvant therapy in combination with platinum doublet chemotherapy for up to 3 cycles in members with early stage (IB-IIIA) NSCLC with tumor size ≥4 cm that is negative for EGFR and ALK mutation, regardless of the tumor PD-L1 status.<br>a.For members with recurrent/metastatic NSCLC that is negative for EGFR and ALK genomic alterations, who have experienced disease progression on platinum-based chemotherapy, except for prior treatment failure with Opdivo (nivolumab) or another checkpoint inhibitor.<br>b.For members, whose cancer is positive for EGFR/ALK genomic alterations and who have experienced disease progression on targeted therapy and platinum-based therapy, except for prior treatment failure with Opdivo (nivolumab) or another checkpoint inhibitor.<br>H.Colorectal Cancer<br>1.NOTE: Per NCH Pathway & NCH Policy, Opdivo (nivolumab) +/- Yervoy (ipilimumab) is a Non-Preferred regimen for the treatment of For metastatic MSI-High colorectal cancer, the preferred Checkpoint Inhibitor in this setting is Keytruda (pembrolizumab).<br>3.Opdivo (nivolumab) will be used as a single agent or in combination with Yervoy (ipilimumab) AND<br>4.The member has not had disease progression on prior therapy with Opdivo (nivolumab) or another checkpoint inhibitor, e.g., Keytruda (pembrolizumab) or Jemperli (dostarlimab-gxly). | Per NCH Pathway exclusion |
| UM ONC_1274 | Opdivo (nivolumab) | Positive change | Add inclusion criteria:<br>Urothelial Carcinoma including Upper Tract and Urethral Carcinomas<br>4.Opdivo (nivolumab) may be used as monotherapy for members with high-risk, non-muscle invasive bladder cancer, with Tis with or without papillary tumors, who are not eligible for cystectomy, and is refractory to/not responding to treatment with BCG. | Per FDA labeling |
| UM ONC_1279 | Cotellic (cobimetinib) | Positive change | Remove inclusion criteria:<br>B.Malignant Melanoma<br>2.NOTE 2: Per NCH Policy & NCH Pathway, Zelboraf (vemurafenib) in combination with a MEK inhibitor (e.g., cobimetinib) is a non-preferred regimen/ combination for use as adjuvant therapy in BRAF V600E or V600K mutation positive resected stage III melanoma; Opdivo (nivolumab) for 1 year is the preferred option in this clinical setting. This recommendation is based on the lack of Level 1 evidence to support the superiority of the above combination over 1 year of adjuvant therapy with Opdivo (nivolumab) or Keytruda (pembrolizumab). | More Cost Effective Alternative(s) |
| UM ONC_1280 | Darzalex and Darzalex Faspro (daratumumab) | Positive change | Remove inclusion criteria:<br>B.Multiple Myeloma<br>1.NOTE 1: The preferred anti-CD38 agent for Multiple Myeloma, per NCH policy and NCH pathway, are Darzalex and Darzalex Faspro (daratumumab IV/SC) over Sarclisa (isatuximab). This recommendation is based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) that shows superior outcomes with Sarclissa (isatuximab)-based regimens over Darzalex (daratumumab)-based regimens. | Per NCH Pathway expansion |
| UM ONC_1280 | Darzalex and Darzalex Faspro (daratumumab) | Negative change | Add inclusion criteria:<br>4.NOTE: Per NCH Pathway & NCH Policy, Daratumumab + Selinexor+/- Dexamethasone is a Non-Preferred regimen for the treatment of relapsed/refractory MM. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) demonstrating superiority compared to NCH Preferred regimens. Please refer to NCH Pathway for the preferred treatments recommended for use in relapsed/refractory MM. | Per NCH Pathway exclusion |
| UM ONC_1280 | Darzalex and Darzalex Faspro (daratumumab) | Positive change | Add inclusion criteria:<br>3.Daratumumab may be used in members with relapsed/refractory multiple myeloma as a part of the following preferred NCH pathway regimens:<br>d.Daratumumab + Bortezomib +/- Cyclophosphamide +/- Steroid | Per Compendia Listing |

| | | | | |
|---|---|---|---|---|
| UM ONC_1299 | Tecentriq (atezolizumab) | Positive change | Remove inclusion criteria:<br>B.Urothelial carcinoma of the bladder, and other urothelial carcinomas<br>1.NOTE: Per NCH Policy & NCH Pathway, Keytruda (pembrolizumab) is the preferred agent over other PD-1 or PD-L1 inhibitors [i.e., Opdivo (nivolumab), Tecentriq (atezolizumab), Bavencio (avelumab), Imfinzi (durvalumab)], for initial and subsequent therapy in the recurrent/metastatic setting.<br>C.Non-Small Cell Lung Cancer (NSCLC)<br>NOTE: Per NCH Policy & NCH Pathway, Keytruda- given with or without chemotherapy as appropriate- is the preferred immunotherapy agent over other PD-1 or PD-L1 inhibitors [e.g. Opdivo (nivolumab), Tecentriq (atezolizumab)], for initial and subsequent therapy in metastatic/recurrent NSCLC. | Per NCH Pathway expansion |
| UM ONC_1299 | Tecentriq (atezolizumab) | Positive change | Add inclusion criteria:<br>B.Urothelial carcinoma of the bladder, and other urothelial carcinomas<br>a.First line treatment in members who are ineligible for cisplatin chemotherapy AND whose tumors express PD-L1 (CPS or TPS of >/=1%) OR for members who are not eligible for any platinum containing chemotherapy regardless of PD-L1 tumor status. | Per FDA labeling |
| UM ONC_1308 | Folotyn (pralatrexate) | No Clinical Changes | N/A | N/A |
| UM ONC_1309 | Iressa (gefitinib) | Negative change | Add inclusion criteria:<br>B.Non-Small Cell Lung Cancer (NSCLC)<br>1.NOTE: The preferred agent, per NCH policy & NCH Pathway, Iressa (gefitinib) is a Non- Preferred drug for first line therapy of recurrent/metastatic EGFR mutation positive Non-Small Cell Lung Cancer. The preferred treatment in the above setting is Tagrisso (osimertinib). This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show Iressa (gefitinib) is superior to Tagrisso (osimertinib). Please see UM ONC_1287 Tagrisso (osimertinib) policy.<br>1.Iressa (gefitinib) may be used as a single agent in members with a known EGFR exon 19 deletions or exon 21 (L858R) sensitizing mutation as subsequent line therapy for recurrent or metastatic NSCLC. Iressa (gefitinib) may be used as first line therapy in a member who has a contraindication/intolerance to Tagrisso (osimertinib). | Per NCH Pathway exclusion |
| UM ONC_1312 | Odomzo (sonidegib) | Negative change | Add inclusion criteria:<br>B.Basal Cell Skin Cancer (BCC)<br>1.Odomzo (sonidegib) may be used as monotherapy in a member with ~~The member has~~ locally advanced or ~~metastatic~~ local recurrent BCC not amenable to or a candidate for curative surgeryand/or radiation therapy. | Per FDA labeling |
| UM ONC_1316 | Nerlynx (neratinib) | Positive change | Add inclusion criteria:<br>B.Breast Cancer<br>2.NOTE: For members with metastatic HER-2 + breast cancer, with disease progression on ≥ prior therapies, Tykerb (lapatinib) + chemotherapy/endocrine therapy, is the preferred anti-HER-2 TKI-Tyrosine Kinase Inhibitor. This recommendation is based on our analysis of the NALA trial which showed no significant Overall Survival benefit for the use of Nerlynx (neratinib) when compared to Tykerb (lapatinib). | Per NCH Pathway expansion |
| UM ONC_1316 | Nerlynx (neratinib) | Negative change | Add exclusion criteria:<br>D.Treatment exceeds the maximum limit of ~~180~~126 (40 mg) tablets/month. | Per FDA labeling |
| UM ONC_1326 | Vyxeos (daunorubicin and cytarabine liposomal) | Negative change | Remove inclusion criteria:<br>B.Acute Myeloid Leukemia (AML)<br>1.Vyxeos (daunorubicin and cytarabine liposomal) may be used for induction and consolidation therapy for members aged 60 years or older, who have newly diagnosed, therapy-related AML or ~~de novo~~ AML with MDS-associated cytogenetic abnormalities. | Per FDA labeling |
| UM ONC_1330 | Besponsa (inotuzumab ozogamicin) | Positive change | Remove inclusion criteria:<br>B.Acute Lymphoblastic Leukemia (ALL)<br>1.NOTE: Per NCH Policy & NCH Pathway, Blincyto (blinatumomab) is the preferred agent for relapsed/refractory B-ALL (Philadelphia chromosome positive or negative) and Besponsa (inotuzumab ozogamicin) is non-preferred. | Per NCH Pathway expansion |
| UM ONC_1330 | Besponsa (inotuzumab ozogamicin) | Negative change | Add inclusion criteria:<br>2.NOTE: Per NCH Pathway & NCH Policy, Inotuzumab Ozogamicin + Mini-hyperCVD (cyclophosphamide, dexamethasone, vincristine, methotrexate, cytarabine) is a Non-Preferred regimen for the treatment of B cell ALL. 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 ALL. | Per NCH Pathway exclusion |

| | | | | |
|---|---|---|---|---|
| UM ONC_1331 | Calquence (acalbrutinib) | Positive change | Add inclusion criteria:<br>B.Mantle Cell Lymphoma (MCL)<br>1.Calquence (acalabrutinib) may be used as monotherapy in relapsed/refractory Mantle Cell Lymphoma in members who have received one prior chemoimmunotherapy, including rituximab containing regimen (e.g., RCHOP, RDHAP, BR). | Per Compendia Listing |
| UM ONC_1331 | Calquence (acalbrutinib) | Negative change | Add inclusion criteria:<br>CLL<br>2.NOTE: Calquence (acalabrutinib) use in combination with Gazyva (obinutuzumab) or Rituxan/rituximab biosimilar, is not supported by NCH policy. Per NCH Policy and NCH Pathway, single agent Calquence (acalabrutinib) is as effective as [Calquence (acalabrutinib) + Gazyva (obinutuzumab)/other anti-CD 20 antibody]. | Per NCH Pathway exclusion |
| UM ONC_1347 | Lorbrena (lorlatinib) | Negative change | Add inclusion criteria:<br>NSCLC<br>2.NOTE: Per NCH Pathway & NCH Policy, Lorbrena (lorlatinib) is a Non-Preferred drug for the initial treatment of anaplastic lymphoma kinase (ALK) positive NSCLC. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior clinical outcomes with Lorbrena (lorlatinib) compared to NCH Preferred regimens. Preferred first line agents are alectinib or brigatinib | Per NCH Pathway exclusion |
| UM ONC_1349 | Talzenna (talazoparib) | Positive change | Add inclusion criteria:<br>B.Breast Cancer<br>1.Talzenna (talazoparib) is not recommended for use when a PARP inhibitor is indicated for use in BRCA1/2 + (either germline or somatic BRCA1/2 + ) metastatic breast cancer. | Per FDA labeling |
| UM ONC_1349 | Talzenna (talazoparib) | Negative change | Add exclusion criteria:<br>A.Disease progression while taking Talzenna (talazoparib) or another PARP inhibitor [i.e.,Lynparza (Olaparib)].<br>B.Concurrent use with other chemotherapy.<br>C.Dosing exceeds single dose limit of Talzenna (talazoparib) 1 mg.<br>D.Treatment exceeds the maximum limit of 120 (0.25 mg), 60 (0.5 mg), 30 (0.75 mg), 30 (1 mg) capsules per month. | Per FDA labeling |
| UM ONC_1350 | Vitrakvi (larotrectinib) | No Clinical Changes | N/A | N/A |
| UM ONC_1366 | Inrebic (fedratinib) | Negative change | Add inclusion criteria:<br>2.Inrebic (fedratinib) may be used as a single agent in a member with primary myelofibrosis or secondary myelofibrosis (e.g., post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis) AND a platelet count of ≥ 50 × 109/L prior to start of treatment | Per FDA labeling |
| UM ONC_1374 | Balversa (erdafitinib) | No Clinical Changes | N/A | N/A |
| UM ONC_1395 | Clolar (clofarabine) | Positive change | Add inclusion criteria:<br>B.Acute Lymphoblastic Leukemia (ALL)<br>1.Member has relapsed/refractory Acute Lymphoblastic Leukemia, and Clolar (clofarabine) is being used a single agent or as part of a multi-agent regimen (e.g., clofarabine + cyclophosphamide + etoposide).<br>C.Acute Myeloid Leukemia (AML)<br>1.Member has relapsed/refractory Acute Myeloid Leukemia, and Clolar (clofarabine) is being used either as a single agent or as a part of a multi-agent regimen (e.g., clofarabine + cytarabine +/- idarubicin). | Per Compendia Listing |
| UM ONC_1397 | Mektovi (binimetinib) | Negative change | Add exclusion criteria:<br>A.Disease progression on the same regimen or with another combination of a BRAF (i.e., vemurafenib, dabrafenib) inhibitor + MEK inhibitor (i.e., trametinib or cobimetinib). | Per FDA labeling |
| UM ONC_1398 | Pemazyre (pemigatinib) | Negative change | Add inclusion criteria:<br>B.Cholangiocarcinoma<br>b.A positive test for FGFR2- fibroblast growth factor receptor 2-gene fusion or rearrangement is confirmed in the tumor cell by an approved test (Foundation One CDX test or another gene sequencing test). | Per FDA labeling |
| UM ONC_1399 | Photofrin (porfimer) | Positive change | Add inclusion criteria:<br>1.Photofrin (porfimer) will be used as photodynamic therapy for the following conditions:<br>a.In members with low-risk superficial basal cell skin cancer , actinic keratoses, or squamous cell carcinoma in situ (Bowen's disease) AND<br>b.The member is not a candidate for surgery and/or radiation therapy. | Per Compendia Listing |

| | | | | |
|---|---|---|---|---|
| UM ONC_1412 | Monjuvi (tafasitamab-cxix) | Positive change | Remove inclusion criteria:<br>B. Diffuse Large B Cell Lymphoma (DLBCL)<br>b. Is ineligible for/failed autologous or allogeneic hematopoietic stem cell transplant<br>AND<br>c. Has had an inadequate response to 2 or more salvage chemoimmunotherapy regimens in the relapsed/refractory setting (e.g. R-ICE, R-DHAP, R-ESHAP,R-EPOCH, or R-GDP). | Per Compendia Listing |
| UM ONC_1416 | Onureg (azacitidine oral) | Negative change | Add inclusion criteria:<br>B.Acute Myeloid Leukemia<br>1.NOTE: Per NCH Pathway & NCH Policy, Onureg (azacitidine oral) is a Non-Preferred drug for the treatment of AML.<br>a.Onureg (azacitidine oral) may be used as a single agent as maintenance therapy in a member with AML in first complete remission following induction therapy who are unable to receive or ar considered clinically unsuitable to receive 3 or more cycles of consolidation therapy after induction and achievement of CR (e.g., HIDAC consolidation). This recommendation is based on the key finding in the pivotal QUAZAR study: Patients who received 3 or more cycles of consolidation therapy had superior outcomes with placebo than with Onureg (see reference below).<br>C.Myelodysplastic Syndromes (MDS)<br>1.NOTE: Per NCH Pathway & NCH Policy, Onureg (azacitidine oral) is not recommended for the treatment of MDS. | Per NCH Pathway exclusion |
| UM ONC_1416 | Onureg (azacitidine oral) | Negative change | Add exclusion criteria:<br>A.In light of FDA warnings for increased mortality risk in patients with MDS, Onureg (azacitidine oral) is not recommended and cannot be substituted for other hypomethylating products (e.g., intravenous azacitidine/decitabine) for the treatment of MDS. | Per FDA labeling |
| UM ONC_1424 | Cosela (trilaciclib) | Negative change | Add inclusion criteria:<br>1.Cosela (trilaciclib) is not recommended for use to prevent chemotherapy induced myelosuppression in extensive stage SCLC per NCH Policy. | More Cost Effective Alternative(s) |
| UM ONC_1425 | Fotivda (tivozanib) | Negative change | Add inclusion criteria:<br>B.Renal Cell Carcinoma (RCC)<br>Fotivda (tivozanib) may be used as a single agent for members with metastatic/unresectable clear cell renal cell carcinoma who have experienced disease progression on, a VEGFR Tyrosine Kinase Inhibitor (e.g., lenvatinib, axitinib, cabozantinib, pazopanib, or bevacizumab) AND one or more Immune Checkpoint Inhibitor (e.g., pembrolizumab, nivolumab, avelumab, ipilimumab). | Per Clinical Trial Analysis/Criteria |
| UM ONC_1425 | Fotivda (tivozanib) | Positive change | Remove inclusion criteria:<br>a.Member's renal cell carcinoma is favorable or intermediate risk based on the IMDC criteria | Per FDA labeling |
| UM ONC_1429 | Abecma (idecabtagene vicleucel) | Negative change | Add exclusion criteria:<br>C.The member does NOT have measurable disease defined as any of the following :<br>1.Serum M-protein greater or equal to 1.0 g/dL<br>2.Urine M-protein greater or equal to 200 mg/24 h<br>3.Serum free light chain (FLC) assay: involved FLC level greater or equal to 10 mg/dL (100 mg/L) provided serum FLC ratio is abnormal.<br>D.The member has solitary plasmacytomas or non-secretory myeloma without other evidence of measurable disease. | Per Clinical Trial Analysis/Criteria |
| UM ONC_1455 | Scemblix (asciminib) | Positive change | Add inclusion criteria:<br>B.Chronic Myeloid Leukemia (CML)<br>b.In a member with CML and the T315I mutation | Per FDA labeling |