| Policy # | Policy Name | Type of Change | Brief Description of Policy Change | Reason for Changes |
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| UM ONC_1262 | Imbruvica (ibrutinib) | Positive change | Add inclusion criteria:<br>F.Chronic Graft Versus Host Disease (cGVHD)<br>1.Imbruvica (ibrutinib) may be used as monotherapy or in combination with systemic corticosteroids for chronic GVHD after failure of one or more lines of therapy, including systemic corticosteroids. | Per FDA labeling |
| UM ONC_1299 | Tecentriq (atezolizumab) | Positive change | Add inclusion criteria:<br>C.Non-Small Cell Lung Cancer (NSCLC)<br>2.For members with stage II-IIIA NSCLC whose tumors have PD-L1 expression on ≥ 1% of tumor cells, Tecentriq (atezolizumab) may be used as adjuvant treatment in combination with platinum-based chemotherapy for up to 4 cycles followed by single agent Tecentriq (atezolizumab) for up to 16 cycles (1 cycle duration= 21 days). | New FDA Indication |
| UM ONC_1328 | Verzenio (abemaciclib) | Positive change | Add inclusion criteria:<br>B.Breast Cancer<br>1.The member has node positive, ER/PR positive, HER2 negative high risk early stage breast cancer (high risk is defined as ≥4 positive axillary lymp nodes, tumor size ≥5 cm, histologic grade 3, or centrally tested Ki-67 ≥20%) AND Verzenio (abemaciclib) will be used in combination with tamoxifen or an aromatase inhibitor as adjuvant treatment for up to 2 years<br>2.a.Confirmed ER /PR positive and HER2 negative breast cancer AND | New FDA Indication |
| UM ONC_1328 | Verzenio (abemaciclib) | Negative change | Add exclusion criteria:<br>A.Disease progression on or after prior therapy with Verzenio (abemaciclib), Ibrance (pablociclib), or Kisqali (ribociclib) containing regimens, ~~or [fulvestrant + Abemaciclib]~~.<br>B.Dosing exceeds single dose limit of Verzenio (abemaciclib) 200 mg (as monotherapy) or 150 mg (in combination with fulvestrant, tamoxifen, or an aromatase inhibitor). | Per FDA labeling |
| UM ONC_1332 | Lutathera (Lutetium Lu 177 dotatete) | No Clinical Changes | N/A | N/A |
| UM ONC_1351 | Xospata (Gilteritinib) | Positive change | Remove exclusion criteria:<br>A.Concurrent use with other strong inhibitors or inducers of P glycoprotein (P-gp) or strong inducers of cytochrome P450 (CYP)3A.<br>B.The member has uncontrolled infection or Long QT Syndrome or left ventricular ejection fraction that is < 45% at screening. | Other: per committee |
| UM ONC_1353 | Cablivi (caplacizumab-yhdp) | Positive change | Add inclusion criteria:<br>B.Acquired Thrombotic Thrombocytopenic Purpura (aTTP)<br>1.The member has aTTP and Cablivi (caplacizumab-yhdp) is being used in combination with plasma exchange and immunosuppressive therapy (e.g ., systemic corticosteroids, rituximab, cyclosporine, cyclophosphamide, vincristine ~~such immunosuppressive therapy~~ may be tapered or discontinued at the physician/provider's discretion). | Per Clinical Trial Analysis/Criteria |
| UM ONC_1353 | Cablivi (caplacizumab-yhdp) | Negative change | Add exclusion criteria:<br>A.An increase in ADAMTS13 activity level from baseline, platelets are within normal limits, or the patient is not at risk of bleeding. | Per Clinical Trial Analysis/Criteria |
| UM ONC_1354 | Daurismo (glasdegib) | Negative change | Add exclusion criteria:<br>C.Dosing exceeds single dose limit of Daurismo (glasdegib) 4100 mg.<br>D.Treatment exceeds the maximum limit of ~~120~~30 (100 mg) or ~~120~~60 (25 mg) tablets/month | Per FDA labeling |
| UM ONC_1354 | Daurismo (glasdegib) | Positive change | Remove inclusion criteria:<br>B.Acute Myeloid Leukemia (AML)<br>1.NOTE: Per NCH Policy & NCH Pathway, Daurismo (glasdegib) is a non-preferred drug for AML in elderly/unfit patients. Daurismo (glasdegib) may be used for the treatment of AML in elderly/medically unfit members if there is a contraindication/intolerance to Venclexta (venetoclax) + Vidaza (azacitidine). Rationale: Venetoclax + Azacitdine is preferred based on clinically meaningful improvements in remission rate and OS over Azacitidine alone.<br>~~In the above members~~ Daurismo (glasdegib) may be used in combination with low-dose cytarabine as remission induction/post induction therapy in elderly or unfit members with AML. ~~being used in combination with low-dose cytarabine.~~ | Per Clinical Trial Analysis/Criteria |
| UM ONC_1379 | Enhertu (fam-trastuzumab deruxtecan-nxk | Negative change | Add inclusion criteria:<br>B.HER-2 positive metastatic/recurrent Breast Cancer<br>3.The member has failed ~~≥ 2~~ at least one prior anti HER-2 therapy~~ics~~ including ~~Kadcyla (ado-trastuzumab)~~ trastuzumab with or without pertuzumab therapy. | Per Clinical Trial Analysis/Criteria |

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| UM ONC_1379 | Enhertu (fam-trastuzumab deruxtecan-nxl | Negative change | Add exclusion criteria:<br>B.Dosing exceeds single dose limit of Enhertu (fam-trastuzumab deruxtecan-nxki) 5.4 mg/kg (for breast cancer) and 6.4 mg/kg (for gastric, esophageal, or GE junction cancer). | Per FDA labeling |
| UM ONC_1380 | Gamifant (emapalumab-lzsg) | Positive change | Add inclusion criteria:<br>B.Hemophagocytic lymphohistiocytosis (HLH)<br>1.The member has primary hemophagocytic lymphohistiocytosis (HLH) AND Gamifant (emapalumab-lzsg) is being used in combination with dexamethasone for disease that is recurrent/refractory/progressing on conventional therapy/intolerant to conventional therapy. Conventional/first line therapy may include immunosuppressive regimens (e.g. corticosteroids, etoposide, cyclosporine, and/or stem cell transplantation). | Per FDA labeling |
| UM ONC_1383 | Sylvant (siltuximab) | Positive change | Add inclusion criteria:<br>B.Idiopathic Multicentric Castleman's Disease (iMCD)<br>1.The member has active multicentric Castleman's disease and is human immunodeficiency virus-1 (HIV-1) and human herpes virus-8 (HHV-8) NEGATIVE AND Sylvant (siltuximab) will be used as monotherapy.<br>~~2.The member is human immunodeficiency virus-1 (HIV-1) or human herpes virus-8 (HHV-8) NEGATIVE.~~ | Per FDA labeling |
| UM ONC_1383 | Sylvant (siltuximab) | Negative change | Add exclusion criteria:<br>A.Sylvant (siltuximab) is being used after disease progression with the same regimen or another interleukin-6 receptor targeted therapy [i.e., Actemra (tocilizumab)]. | Per FDA labeling |
| UM ONC_1387 | Unituxin (dinutuximab) | Negative change | Add inclusion criteria:<br>B.Neuroblastoma<br>1.The member is less than 18 years of age has with unresectable high-risk neuroblastoma | Per FDA labeling |
| UM ONC_1387 | Unituxin (dinutuximab) | Positive change | Add inclusion criteria:<br>5.Unituxin (dinutuximab) is being used in combination with 13-cis-retinoic acid (isotretinoin), granulocyte-macrophage colony-stimulating factor (sargramostim), ~~and~~with or without interleukin-2 (aldesleukin) | Per Clinical Trial Analysis/Criteria |
| UM ONC_1387 | Unituxin (dinutuximab) | Positive change | Remove inclusion criteria:<br>6.The member has contraindications, intolerance, or failure to cyclophosphamide, vincristine, and/or doxorubicin containing chemotherapy. | Per Clinical Trial Analysis/Criteria |
| UM ONC_1387 | Unituxin (dinutuximab) | Negative change | Add exclusion criteria:<br>A.Unituxin (dinutuximab) is being used after disease progression with the same regimen or prior anti-disialoganglioside (GD2) antibody therapy [e.g., Danyelza (naxitamab)]. | Per FDA labeling |
| UM ONC_1396 | Koselugo (selumetinib) | Negative change | Add inclusion criteria:<br>B.Plexiform Neurofibromas (PN)<br>1.Koselugo (selumetinib) will be used as a single agent in ~~children~~ pediatric members 2 to 18 years of age and older | Per FDA labeling |
| UM ONC_1396 | Koselugo (selumetinib) | Negative change | Add exclusion criteria:<br>B.Dosing exceeds single dose limit of Koselugo (selumetinib) 25 mg/m2 (not to exceed 50 mg).<br>C.Treatment exceeds the maximum limit of ~~9~~60 (10 mg) or 120 (25 mg) tablets/month. | Per FDA labeling |
| UM ONC_1407 | Trodelvy (govitecan-hziy) | Negative change | Add inclusion criteria:<br>B.Breast Cancer<br>1.NOTE: Per NCH Policy and NCH Pathway, Trodelvy (sacituzumab govitecan-hzly) is the recommended agent for subsequent line (~~2nd~~ third line and beyond) therapy of metastatic, triple negative breast cancer.<br>a.Trodelvy use, as a single agent, is supported when ALL of the following criteria are met:<br>i.Member has recurrent/metastatic triple negative (ER/PR/HER-2 negative) breast cancer AND<br>ii.Member has experienced disease progression on ~~one~~ two or more lines of therapy, at least one of the regimens is for metastatic triple negative breast cancer | Per FDA labeling |
| UM ONC_1413 | Tecartus (brexucabtagene autoleucel) | Positive change | Add inclusion criteria:<br>C.Acute Lymphoblastic Leukemia (ALL)<br>1.Tecartus (brexucabtagene autoleucel) may be used when the following criteria are met:<br>a.Member is an adult, 18 years of age and older, with Acute Lymphoblastic Leukemia with confirmed documentation of CD19 tumor expression (demonstrated in bone marrow or peripheral blood by flow cytometry) AND<br>b.Member has experienced disease relapse at least 100 days from allogeneic stem cell transplantation (SCT) at the time of infusion OR<br>c.Member has relapsed/refractory Philadelphia chromosome-negative B-ALL that has progressed after failure with at least 2 lines of systemic therapy, including Blincyto (blinatumomab) OR<br>d.Member has relapsed/refractory Philadelphia chromosome-positive B-ALL that has progressed after failure with at least 2 different TKI-containing regimens. | New FDA Indication |

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| UM ONC_1413 | Tecartus (brexucabtagene autoleucel) | Negative change | Add exclusion criteria:<br>A.Tecartus (brexucabtagene autoleucel) is being used after disease progression on or after CAR-T cell therapy directed towards CD19 antigen (e.g., Kymriah, Breyanzi, Yescarta). | Per FDA labeling |
| UM ONC_1413 | Tecartus (brexucabtagene autoleucel) | Positive change | Remove exclusion criteria:<br>C.Diagnosis of Mantle Cell Lymphoma not confirmed by either a positive cyclin D1 expression or a positive t(11;14) translocation in lymphoma cells. | Other: per committee |