Policy Name	Type of Change	Brief Description of Policy Change	Reason for Changes
Bevacizumab Products	Negative change	Add inclusion criteria: C.Cervical Cancer 1.For members with metastatic/recurrent/unresectable cervical cancer with tumor PD-L1 staining showing a CPS of less than 1%, ~~Avastin (bevacizumab)/bevacizumab biosimilar~~ Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr) may be used as first line/initial therapy in any one of the following regimens: a. ~~Avastin (bevacizumab)/bevacizumab biosimilar~~ Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr) + cisplatin/carboplatin + paclitaxel b. ~~Avastin (bevacizumab)/bevacizumab biosimilar~~ Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr) + topotecan + paclitaxel AND 2.Avastin (bevacizumab), Alymsys (bevacizumab-maly), and Vegzelma (bevacizumab-adcd) may be used only when there is documented confirmation of a contraindication/intolerance to Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr). D.Colorectal Cancer 1.The member has unresectable advanced or metastatic colorectal cancer and ~~Avastin (bevacizumab)/bevacizumab biosimilar~~ Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr) is being used as ONE of the following: a.As initial therapy in combination with capecitabine or with FOLFOX, FOLFIRI, FOLFIRINOX (fluorouracil, leucovorin, irinotecan, and oxaliplatin), 5-FU/LV (fluorouracil and leucovorin), or CapeOX (capecitabine and oxaliplatin). b.As subsequent line of therapy given in combination with FOLFOX, FOLFIRI, XELIRI, and XELOX/CapeOX. c. ~~Avastin (bevacizumab)/bevacizumab biosimilar~~ Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr) may be used for up to 2 lines of therapy in the metastatic setting or up to 3 lines of therapy for Avastin (bevacizumab)/bevacizumab biosimilar + Lonsurf (trifluridine and tipiracil) AND d. Avastin (bevacizumab), Alymsys (bevacizumab-maly), and Vegzelma (bevacizumab-adcd) may be	Step Therapy Criteria
Bevacizumab Products	Negative change	E.Glioblastoma 1.The member has glioblastoma, anaplastic astrocytoma, or high-grade glioma and Avastin (bevacizumab)/bevacizumab biosimilar is being used as a single agent OR 2. ~~Avastin (bevacizumab)/bevacizumab biosimilar~~ Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr) may be used in combination with irinotecan, carboplatin, carmustine, lomustine, or temozolomide for recurrent glioblastoma, anaplastic astrocytoma, or high-grade glioma AND 2.3. Avastin (bevacizumab), Alymsys (bevacizumab-maly), and Vegzelma (bevacizumab-adcd) may be used only when there is documented confirmation of a contraindication/intolerance to Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr). F.Hepatocellular Carcinoma 1.Member has metastatic/inoperable/advanced hepatocellular carcinoma (Child-Pugh Class A only) and ~~Avastin (bevacizumab)/bevacizumab biosimilar~~ Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr) will be used in combination with Tecentriq (atezolizumab) for initial therapy AND 1.2. Avastin (bevacizumab), Alymsys (bevacizumab-maly), and Vegzelma (bevacizumab-adcd) may be used only when there is documented confirmation of a contraindication/intolerance to Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr).. G.Non-Small Cell Lung Cancer (NSCLC) 1. ~~Avastin (bevacizumab)/bevacizumab biosimilar~~ Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr)- based regimens are Not Approvable for metastatic Non-Small Cell Lung Cancer with the following exception: a.For first/initial line therapy for members with recurrent/metastatic non-squamous Non-Small Cell Lung Cancer as a part of [carboplatin + paclitaxel + bevacizumab + atezolizumab] followed by maintenance atezolizumab ± bevacizumab; the above regimen is Not Approvable if member has experienced disease progression on prior Immune Checkpoint Inhibitor therapy. AND b. Avastin (bevacizumab), Alymsys (bevacizumab-maly), and Vegzelma (bevacizumab-adcd) may be	Step Therapy Criteria

Bevacizumab Products	Negative change	Add inclusion criteria: H.Ovarian Cancer 1. For the clinical settings below, Avastin (bevacizumab), Alymsys (bevacizumab-maly), and Vegzelma (bevacizumab-adcd) may be used for the treatment of Ovarian Cancer only when there is documented confirmation of a contraindication/intolerance to Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr). 2.The member has recurrent or metastatic ovarian cancer and Avastin (bevacizumab)/bevacizumab biosimilar may be used in any of the following clinical settings: a.For initial/first line therapy of stage II- IV, Avastin (bevacizumab)/bevacizumab biosimilar may be used with chemotherapy. b. ~~Avastin (bevacizumab)/bevacizumab biosimilar~~ Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr) may be used for maintenance therapy after complete/partial response to primary chemotherapy + bevacizumab, for stage II-IV disease as follows: i.As monotherapy for BRCA 1 or 2 Wild-Type or Unknown, HRD negative (Homologous Recombination Deficiency negative) or HRD unknown OR ii.In combination with Lynparza (olaparib) for BRCA 1 or 2 mutation (germline or somatic) or HRD positive. 3.For therapy of relapsed/recurrent ovarian cancer, Avastin (bevacizumab)/bevacizumab biosimilar may be used as monotherapy or with chemotherapy. I.Renal Cell Carcinoma 1.The member has recurrent or metastatic disease and ~~Avastin (bevacizumab)/bevacizumab biosimilar is being~~ Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr) may be used as a single agent for members who have experienced disease progression on an oral TKI (e.g., pazopanib) AND an Immune Checkpoint Inhibitor (e.g., pembrolizumab) AND 2. Avastin (bevacizumab), Alymsys (bevacizumab-maly), and Vegzelma (bevacizumab-adcd) may be used only when there is documented confirmation of a contraindication/intolerance to Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr).	Step Therapy Criteria
Bevacizumab Products	Negative change	Add exclusion criteria: B.Use of Avastin (bevacizumab), Alymsys (bevacizumab-maly), or Vegzelma (bevacizumab-adcd) without a documented confirmation of a contraindication/intolerance to Mvasi (bevacizumab-awwb)/Zirabev (bevacizumab-bvzr).	Step Therapy Criteria

Myeloid Growth Factors	Negative change	B.MGF in Members Receiving Concurrent Chemoradiation 1. For members on concurrent chemoradiation, the use of short-acting MGFs [e.g., Granix (tbo-filgrastim), Zarxio (filgrastim-sndz), Nivestym (filgrastim-aafi), Releuko (filgrastim-ayow)] may be used on a case-by-case basis. If approved, it is recommended that concurrent radiation be held during MGF administration AND 2. Neupogen (filgrastim) or Leukine (sargramostim) may be used only if there is documented confirmation of a contraindication/intolerance to Granix (tbo-filgrastim), Zarxio (filgrastim-sndz), Nivestym (filgrastim-aafi), or Releuko (filgrastim-ayow). 1. ~~For members on concurrent chemoradiation, the use of short acting MGF [e.g., Neupogen (filgrastim)/filgrastim biosimilars and Leukine (sargramostim)] may be Approvable on a case-by case basis; if approved it is suggested that concurrent radiation be held during this G-CSF administration.~~ ~~2.NOTE: For members on concurrent chemoradiation, the use of long acting MGF [e.g., Neulasta (pegfilgrastim)/pegfilgrastim biosimilars or Rolvedon (eflapegrastim)] is Not Approvable per NCH policy. This Policy Position is based on the lack of data documenting the safety of administering long acting MGFs in members receiving concurrent chemo-radiation. Please refer to NCH alternative agents/regimens recommended by NCH, including but not limited to regimens available at http://pathways.newcenturyhealth.com.~~ C.Myelodysplastic Syndromes (MDS) 1.A short acting MGF ~~(e.g., Neupogen (filgrastim)/filgrastim biosimilars)~~ is being used in combination with lenalidomide and/or epoetin or darbepoetin alpha in members with no response to erythropoietin alone OR 2.The member has MDS and a short acting MGF (e.g., Neupogen (filgrastim)filgrastim biosimilars) is being used for neutropenia AND prevention of infections AND. a. Neupogen (filgrastim) may be used only if there is documented confirmation of a contraindication/intolerance to Granix (tbo-filgrastim), Zarxio (filgrastim-sndz), Nivestym (filgrastim-aafi), or Releuko (filgrastim-ayow).	Step Therapy Criteria
Myeloid Growth Factors	Negative change	Add inclusion criteria: D.Peripheral Blood Stem Cell (PBSC) Mobilization 1.A short acting MGF ~~(e.g., Neupogen (filgrastim)/filgrastim biosimilars)~~ may be used for PBSC mobilization prior to and during leukapheresis in members undergoing an autologous PBSC collection and therapy AND. 2. Neupogen (filgrastim) or Leukine (sargramostim) may be used only if there is documented confirmation of a contraindication/intolerance to Granix (tbo-filgrastim), Zarxio (filgrastim-sndz), Nivestym (filgrastim-aafi), or Releuko (filgrastim-ayow).	Step Therapy Criteria

Myeloid Growth Factors	Positive change	Add inclusion criteria: E.Prophylaxis/Prevention of Febrile Neutropenia from Chemotherapy 1. ~~The member has a solid tumor or non-myeloid malignancy and is receiving MGF for any of the following:~~ ~~b.MGF is being used for chemotherapy with high-risk (greater than 20%) for febrile neutropenia (please refer to Attachment C for a list of drugs/regimens with high-risk for febrile neutropenia) OR~~ ~~c.MGF is being used with chemotherapy with an intermediate risk (10% to 20%) for febrile neutropenia AND the member has ONE or more of the following risk factors:~~ ~~i.Age greater than or equal to 65 years; extensive prior chemotherapy or radiation therapy; persistent/pre-existing neutropenia; bone marrow involvement by tumor; recent surgery and/or open wounds; liver dysfunction (Bili greater than 2.0), or renal dysfunction (CrCl less than 50).~~ ~~2.MGF use is supported as Secondary Prophylaxis for members with solid tumors or non-myeloid malignancies who experienced any of the following:~~ ~~a.A prior episode of febrile neutropenia with the current chemotherapy OR~~ ~~b.A neutropenic event leading to chemotherapy dose delay or dose decrease in the curative intent setting.~~ ~~3.NOTE 1: NCH Policy MGF (either short acting or long acting) use for the treatment of afebrile neutropenia is Not Approvable. This position is supported by Level 1 evidence showing no clinical benefit from MGF therapy in the above clinical setting. Please see Attachment D for MGF indications for febrile neutropenia primary and secondary prophylaxis.~~ ~~4.NOTE 2: Per NCH Policy, the use of short acting MGF [e.g., Neupogen (filgrastim)/filgrastim biosimilars and Leukine (sargramostim)] is Approvable for the above indications. Long Acting MGFs (pegfilgrastim/pegfilgrastim biosimilars and Rolvedon (eflapegrastim)] are Approvable only if there is documented confirmation of a contraindication/intolerance to a short acting MGF, member is unable to self-administer due to limitations, AND the member is unable to travel to the office for daily injections. Please refer to NCH alternative agents/regimens recommended by NCH, including but not limited to regimens available at http://pathways.newcenturyhealth.com.~~	Step Therapy Criteria
Myeloid Growth Factors	Negative change	E.Prophylaxis/Prevention of Febrile Neutropenia from Chemotherapy 1. The member has a solid tumor or non-myeloid malignancy and MGF will be used as primary prophylaxis for febrile neutropenia from chemotherapy in any of the following clinical settings: b.MGF is being used for chemotherapy with high-risk (greater than 20%) for febrile neutropenia (please refer to Attachment C for a list of drugs/regimens with high-risk for febrile neutropenia) OR c.MGF is being used with chemotherapy with an intermediate risk (10% to 20%) for febrile neutropenia AND the member has ONE or more of the following risk factors: i.Age greater than or equal to 65 years; extensive prior chemotherapy or radiation therapy; persistent/pre-existing neutropenia; bone marrow involvement by tumor; recent surgery and/or open wounds; liver dysfunction (Bili greater than 2.0), or renal dysfunction (CrCl less than 50). OR 2.MGF may be used as secondary prophylaxis for members with solid tumors or non-myeloid malignancies who experienced any of the following: a.A prior episode of febrile neutropenia with the current chemotherapy OR b.A neutropenic event leading to chemotherapy dose delay or dose decrease in the curative intent setting. AND 3.Long-acting MGF [e.g., Neulasta (pegfilgrastim), Fulphila (pegfilgrastim-jmdb), Udenyca (pegfilgrastim-cbqv), Ziextenzo (pegfilgrastim-bmez), Nyvepria (pegfilgrastim-apgf))] may be used only if there is documented confirmation of a contraindication/intolerance to Granix (tbo-filgrastim), Zarxio (filgrastim-sndz), Nivestym (filgrastim-aafi), or Releuko (filgrastim-ayow)]. AND 4.The member is unable to self-administer due to limitations, and the member is unable to travel to the office for daily injections. F.Treatment of Febrile Neutropenia 1.Member has documented febrile neutropenia as defined by the Infectious Disease Society of America as: An ANC (Absolute Neutrophil Count) of less than 1,000 cells/micoL AND a single	Step Therapy Criteria

Myeloid Growth Factors	Negative change	Add exclusion criteria: A.MGF use with Low FN Risk regimens. An exception will be made in the following clinical settings: 1. If a member experienced dose reduction AND cycle delay with curative intent chemotherapy OR 2.A member had a prior episode of febrile neutropenia on the same regimen. B.Use of Neupogen (filgrastim) or Leukine (sargramostim) without a documented confirmation of a contraindication/intolerance to Granix (tbo-filgrastim), Zarxio (filgrastim-sndz), Nivestym (filgrastim-aafi), or Releuko (filgrastim-ayow). C.Use of Fylnetra and Stimufend without a documented confirmation of a contraindication/intolerance to a short-acting MGF [e.g, Neupogen (filgrastim)/filgrastim biosimilar] OR to Neulasta (pegfilgrastim), Fulphila (pegfilgrastim-jmdb), Udenyca (pegfilgrastim-cbqv), Ziextenzo (pegfilgrastim-bmez), or Nyvepria (pegfilgrastim-apgf)), D.Use long acting MGF [e.g., Neulasta (pegfilgrastim)/pegfilgrastim biosimilars or Rolvedon (eflapegrastim)] in members on concurrent chemoradiation, E.Use for prevention of febrile neutropenia when CDK4/6 inhibitors are being used.	Step Therapy Criteria
Rituxan Products	Negative change	B.CD-20 positive B-Cell Non-Hodgkin's Lymphomas (NHL) and Acute Lymphoblastic Leukemia (B-ALL) 1.The member is an adult or pediatric member greater than or equal to 6 months of age who has CD20 positive B-cell NHL (e.g., follicular, diffuse large B-cell, Mantle Cell Lymphoma, pediatric aggressive mature B-Cell Lymphomas) or B-ALL and ~~Rituxan (rituximab)/rituximab biosimilar is being~~ Truxima (rituximab-abbs), Ruxience (rituximab-pvvr) , and Riabni (rituximab-arrx) may be used as a single agent or in combination with chemotherapy for ANY of the following: a.Initial therapy (for use in combination with chemotherapy only) OR b.Treatment of relapsed or refractory disease OR c.Maintenance therapy: i.For up to two years for Indolent B-Cell Lymphomas (Follicular B Cell Lymphoma and all subtypes of Marginal Zone Lymphoma). ii.For up to disease progression or intolerable toxicity for Mantle Cell Lymphoma AND. d. Rituxan (rituximab) or Rituxan Hycela (rituximab and hyaluronidase) may be used only if there is documented confirmation of a contraindication/intolerance to Truxima (rituximab-abbs), Ruxience (rituximab-pvvr) , Riabni (rituximab-arrx). C.Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) 1. ~~Rituxan (rituximab)/rituximab biosimilar~~ Truxima (rituximab-abbs), Ruxience (rituximab-pvvr) , and Riabni (rituximab-arrx) may be is being used for first or subsequent line of therapy: a.In combination with chemotherapy OR b.As maintenance therapy for up to 2 years AND c. Rituxan (rituximab) or Rituxan Hycela (rituximab and hyaluronidase) may be used only if there is documented confirmation of a contraindication/intolerance to Truxima (rituximab-abbs), Ruxience (rituximab-pvvr) , Riabni (rituximab-arrx). D.Hodgkin's Lymphoma -Nodular Lymphocyte Predominant CD-20 + Hodgkin's Lymphoma 1.The member has nodular lymphocyte predominant Hodgkin's Lymphoma and ~~Rituxan (rituximab)/rituximab biosimilar is being~~ Truxima (rituximab-abbs), Ruxience (rituximab-pvvr) , and Riabni (rituximab-arrx) may be used as a single agent or in combination with chemotherapy for	Step Therapy Criteria
Rituxan Products	Negative change	Add exclusion criteria: B.Use of Rituxan (rituximab) or Rituxan Hycela (rituximab and hyaluronidase) without a documented confirmation of a contraindication/intolerance to Truxima (rituximab-abbs), Ruxience (rituximab-pvvr), or Riabni (rituximab-arrx).	Step Therapy Criteria

Erbitux (Cetuximab)	Negative change	Add inclusion criteria: C.Head and Neck Cancers 1.The member has squamous cell carcinoma of the head and neck Erbitux (cetuximab) may be used for locally advanced/recurrent/metastatic disease as a single agent, or in combination with chemotherapy. in ANY of the following situations. ~~2.As a part of primary/definitive/curative intent concurrent chemoradiation (Erbitux + Radiation) as a single agent for locally advanced disease OR~~ ~~a.For locally advanced/recurrent/metastatic disease as a single agent, or in combination with chemotherapy.~~ 3.NOTE: Per NCH Policy, [Erbitux (cetuximab) + Taxotere (docetaxel)], and [Erbitux (cetuximab) + Keytruda (pembrolizumab)], ~~and~~ [Erbitux (cetuximab) + Radiation] are not approvable for the treatment of ~~advanced/metastatic~~ head and neck cancers. This policy position is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with any of the above regimens compared to NCH recommended regimens/agents, including but not limited to regimens available at https://pathway.newcenturyhealth.com.	Per NCH Pathway exclusion
Erbitux (Cetuximab)	Negative change	Add exclusion criteria: B. As a single agent or in combination with Ppre/post-operative chemotherapy for potentially resectable liver metastases from KRAS/NRAS wild-type colorectal cancer.	Per Compendia Listing
Trastuzumab Products, Pertuzumab (pertuzumab), and Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf)	Negative change	B.HER-2 Positive Breast Cancer 1.For the treatment of HER-2 positive breast cancer, Herceptin (trastuzumab) and Herceptin Hylecta (trastuzumab hyaluronidase) may be used only when there is documented confirmation of a contraindication/intolerance to a trastuzumab biosimilar therapy [e.g., Ogivri (trastuzumab-dkst), Herzuma (trastuzumab-pkrb), Ontruzant (trastuzumab-dttb), Kanjinti (trastuzumab-anns), or Trazimera (trastuzumab-qyyp)]. Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf) may be used when a combination of [trastuzumab + pertuzumab] is indicated. 1.2.The member has node positive and/or tumor stage T2 or greater HER-2 positive breast cancer AND Herceptin (trastuzumab)/trastuzumab biosimilar +/- Perjeta (pertuzumab) may be used as neoadjuvant treatment OR as adjuvant treatment in members who did not receive neoadjuvant therapy The following chemotherapy regimens are acceptable for use with Herceptin (trastuzumab)/trastuzumab biosimilar +/- Perjeta (pertuzumab) combination therapy as neoadjuvant or adjuvant treatment: a.~~Herceptin (trastuzumab)/T~~ trastuzumab biosimilar +/- Perjeta (pertuzumab) with paclitaxel following AC (doxorubicin + cyclophosphamide) b. ~~Herceptin (trastuzumab)/T~~trastuzumab biosimilar +/- Perjeta (pertuzumab) with docetaxel following AC (doxorubicin + cyclophosphamide) c. ~~Herceptin (trastuzumab)/T~~trastuzumab biosimilar +/- Perjeta(pertuzumab) with docetaxel/paclitaxel d.TCH (docetaxel, carboplatin, and Herceptin (trastuzumab)/tTrastuzumab biosimilar) +/- Perjeta (pertuzumab) e. ~~Herceptin (trastuzumab)/T~~trastuzumab biosimilar with docetaxel and cyclophosphamide. 2.3. ~~Herceptin (trastuzumab)/T~~trastuzumab biosimilar +/- Perjeta (pertuzumab) may be used as continuation adjuvant therapy following adjuvant ~~Herceptin (trastuzumab)/T~~trastuzumab biosimilar +/- Perjeta (pertuzumab) + Chemotherapy. 3.4. ~~Herceptin (trastuzumab)/T~~trastuzumab biosimilar may be used as first line or subsequent line therapy, with or without Perjeta (pertuzumab) for recurrent or metastatic HER-2 positive breast	Step Therapy Criteria
Trastuzumab Products, Pertuzumab (pertuzumab), and Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf)	Negative change	Add exclusion criteria: B.Use of Herceptin (trastuzumab) without a documented confirmation of a contraindication/intolerance to Ogivri (trastuzumab-dkst), Herzuma (trastuzumab-pkrb), Ontruzant (trastuzumab-dttb), Kanjinti (trastuzumab-anns), or Trazimera (trastuzumab-qyyp).	Step Therapy Criteria

Trastuzumab Products~~, Pertuzumab (pertuzumab),~~ and Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf)	Positive change	Remove exclusion criteria: ~~B.Herceptin (trastuzumab)/trastuzumab biosimilar + Keytruda (pertuzumab) is being used in the adjuvant setting without any adjuvant chemotherapy (before/after/during trastuzumab + pertuzumab).~~ C.Herceptin (trastuzumab) / trastuzumab biosimilar ~~Ogivri (trastuzumab-dkst)/Herzuma (trastuzumab-pkrb)/Ontruzant (trastuzumab-dttb)/Kanjinti (trastuzumab-anns)/Trazimera (trastuzumab-qyyp)~~ use in gastric or gastroesophageal junction cancer after disease progression with first line therapy containing trastuzumab.	Per FDA labeling
Erythropoiesis Stimulating Agents (ESA)	Negative change	B.Anemia of Chronic Kidney Disease (CKD) 1.The member has chronic kidney disease defined as GFR less than 60 ml/min over a period of at least three months AND concomitant iron deficiency has been ruled out with a serum ferritin greater than or equal to 30 ng/mL AND/OR transferrin saturation greater than or equal to 20% with levels obtained within the last 12 months) AND 2. For initiation of therapy, a Hgb of less than 10 g/dL is required (levels are obtained within the last 4 weeks) OR 3.For continuation of therapy, a Hgb of 11 g/dL or less is required (levels are obtained within the last 4 weeks) AND 4.Aranesp (darbepoetin alfa) may be used only when there is documented confirmation of a contraindication/intolerance to Epoetin alpha [Epogen and Procrit (epoetin alfa), or Retacrit (epoetin alfa-epbx)]. ~~2.NOTE: Per NCH Policy, Aranesp (darbepoetin alfa) is Not Approvable for the treatment of CKD. The Approvable medications are Retacrit (epoetin alfa-epbx) and Procrit/Epogen (epoetin alfa). This Policy Position is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with Aranesp (darbepoetin alfa) compared to Retacrit (epoetin alfa-epbx) and Procrit/Epogen (epoetin alfa). Please refer to NCH alternative agents/regimens recommended by NCH, including but not limited to regimens available at http://pathways.newcenturyhealth.com.~~ C.Chemotherapy induced anemia (CIA) 1. ~~ESA is being~~ Epogen and Procrit (epoetin alfa) or Retacrit (epoetin alfa-epbx) may be used in members at risk of requiring red blood cell transfusions within 30 days of anemia with solid tumors or non-myeloid malignancies receiving myelosuppressive chemotherapy without curative intent and such chemotherapy is ongoing or has been completed less than or equal to 8 weeks prior to initiation or continuation of ~~ESA~~ Epogen and Procrit (epoetin alfa) or Retacrit (epoetin alfa-epbx), and the member meets the following criteria: a.For initial/continuation requests the baseline Hgb less than 10 g/dL or HCT less than 30 prior to	Step Therapy Criteria
Erythropoiesis Stimulating Agents (ESA)	Negative change	Add exclusion criteria: B.Use of Aranesp (darbepoetin alfa) without a documented confirmation of a contraindication/intolerance to Epogen and Procrit (epoetin alfa) or Retacrit (epoetin alfa-epbx)].	Step Therapy Criteria
Erythropoiesis Stimulating Agents (ESA)	Positive change	Remove exclusion criteria: ~~B.Mircera (epoetin beta) is not indicated in CIA and MDS.~~	Per Clinical Trial Analysis/Criteria

Havalen (eribulin)	Positive change	Remove inclusion criteria: B.Breast Cancer 1.The member has recurrent or metastatic breast cancer, and Halaven (eribulin) is being used as a single agent for members with HER2-negative disease OR 2.The member has recurrent or metastatic breast cancer, and Halaven (eribulin) is being used in combination with trastuzumab for members with HER2-positive disease. ~~3.NOTE: Per NCH Policy, Halaven (eribulin) + Margenza (margetuximab-cmkb) is a Not Approvable non-Preferred regimen for recurrent or metastatic HER2 positive breast cancer. This recommendation policy position is based on the results of the SOPHIA trial (referenced below) which did not demonstrate an overall survival benefit- lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior overall survival outcomes with Margenza (margetuximab-cmkb) + cChemotherapy compared to alternative regimens recommended by NCH (htttp://pathways.newcenturyhealth.com) that use Herceptin (Ttrastuzumab)/Ttrastuzumab-bBiosimilar + cChemotherapy. Please refer to NCH alternative agents/regimens recommended by NCH, including but not limited to regimens available at http://pathways.newcenturyhealth.com.~~	Per Compendia Listing
Bosulif (bosutinib)	Positive change	Remove inclusion criteria: B.Chronic Myelogenous Leukemia (CML) 1.Bosulif (bosutinib) may be used in all phases of Philadelphia chromosome positive or BCR-ABL positive CML, including before and after hematopoietic stem cell transplantation, ~~AND the member has~~ for members with a documented history of disease progression, contraindications, or intolerance to~~ to NCH preferred agents recommended for use in CML~~ generic imatinib . This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) demonstrating superior outcomes with one TKI over another except in members with the applicable BCR-ABL1 mutational analysis outlined below. ~~2.NOTE 1: Per NCH Policy & NCH L1 Pathway, generic imatinib is the preferred agent for first line therapy of BCR-ABL positive CML unless there is documented intolerance, contraindications, or disease progression on generic imatinib. Please refer to NCH policy UM ONC_1177 Gleevec (imatinib mesylate) policy and NCH L1 pathway for the preferred regimens.~~ ~~3.NOTE 2: After failure of first line therapy, the preferred options are Sprycel (dasatinib) (including but not limited to members with Y253H, E255K/V, F359C/I/V) or Tasigna (nilotinib) (including but not limited to members with F317L/V/I/C, T315A, V299L mutations). Please refer to NCH policy UM ONC_1196 Sprycel (dasatinib), UM ONC_1199 Tasigna (nilotinib), and NCH L1 pathway for the preferred regimens.~~ ~~4.2.NOTE 3: After failure of 2 prior Tyrosine Kinase Inhibitors (TKIs), the preferred agent is Scemblix (asciminib). Please refer to NCH policy UM ONC_1455 Scemblix (asciminib) and NCH L1 pathway for the preferred regimens.~~	Step Therapy Criteria
Bosulif (bosutinib)	Negative change	Add exclusion criteria: C.For CML: Contraindicated for use in members with the following mutations: T315I, V299L , G250E, or F317L.	Per Compendia Listing
Cometriq or Cabometyx (cabozantinib)	No Clinical Changes	N/A	N/A

Pomalyst (pomalidomide)	Positive change	Add inclusion criteria: B.Multiple Myeloma 1.Pomalyst (pomalidomide) may be used as follows: a.The member has relapsed or refractory multiple myeloma and has failed 2 prior therapies for myeloma including one proteasome inhibitor & one immunomodulatory agent in ANY of the following regimens: i.In combination with dexamethasone or corticosteroid equivalent unless there is an intolerance/contraindication to a corticosteroid. ii.In combination with Darzalex (daratumumab) +/- dexamethasone iii.In combination with Cytoxan (cyclophosphamide) +/- dexamethasone iv.In combination with Empliciti (elotuzumab) +/- dexamethasone v.In combination with Kyprolis (carfilzomib) +/- dexamethasone. vi.In combination with ixazomib +/- dexamethasone vii.In combination with Velcade (bortezomib) +/- dexamethasone viii.In combination with Sarclisa (isatuximab-irfc) +/- dexamethasone ix.In combination with Xpovio (Selinexor) +/- dexamethasone.	Per Compendia Listing
Pomalyst (pomalidomide)	Negative change	Add exclusion criteria: B.Dosing exceeds single dose limit of Pomalyst (pomalidomide) 4 mg for Multiple Myeloma and 5 mg for Kaposi Sarcoma.	Per FDA labeling
Synribo (omacetaxine)	Negative change	Add exclusion criteria: B.Concurrent use with other anticancer therap ies~~y~~.	Per Clinical Trial Analysis/Criteria
Iclusig (ponatinib)	Positive change	Remove inclusion criteria: B.Chronic Myeloid Leukemia (CML) 1.Iclusig (ponatinib) may be used as single agent for subsequent line therapy if there is documented intolerance, contraindications, or disease progression on generic imatinib and one ~~of the following 2nd generation~~ other Tyrosine Kinase Inhibitors (TKIs): Tasigna (nilotinib) or Sprycel (dasatinib) OR 2.Iclusig (ponatinib) may be used as a single agent for members with T3151 mutation positive CML.	Per FDA labeling
Iclusig (ponatinib)	Positive change	Add inclusion criteria: C.Acute Lymphoblastic Leukemia (ALL) 1.The member has Philadelphia chromosome/BCR-ABL positive ALL and Iclusig (ponatinib) may be used as a single agent or in combination with chemotherapy if there is documented intolerance, contraindications, or disease progression on generic imatinib OR. 2.Iclusig (ponatinib) may be used as a single agent for members with T3151 mutation positive Philadelphia chromosome/BCR-ABL positive ALL.	Per FDA labeling
Iclusig (ponatinib)	Negative change	Add exclusion criteria: B. ~~Iclusig (ponatinib) is not indicated and is not recommended~~ Use of Iclusig (ponatinib) for the treatment of members with newly diagnosed CML/ALL without the T3151 mutation. C.Concurrent use with other anticancer therap ies~~y~~ for the treatment of CML. D.Use of Iclusig (ponatinib) in Philadelphia chromosome/BCR-ABL negative ALL or T3151 mutation negative CML or ALL.	Per FDA labeling

Mekinist (trametinib)	Positive change	B.Malignant Melanoma 1.Mekinist (trametinib) may be used as adjuvant treatment, following complete resection, in combination with Tafinlar (dabrafenib) for melanoma with BRAF V600E or V600K mutations OR 2.Mekinist (trametinib) may be used in combination with Tafinlar (dabrafenib) in members in members with unresectable or metastatic BRAF V600E or V600K mutation positive melanoma and who have intolerance to/contraindication to ~~the use of the preferred MEK and BRAF inhibitor combination,~~ Cotellic (cobimetinib) + Zelbroaf (vemurafenib). ~~3.NOTE: Per NCH Policy, Mekinist (trametinib) + Tafinlar (dabrafenib) is a non-preferred regimen for the treatment of metastatic BRAF V600E or V600K mutation positive melanoma. The preferred oral combination, is Cotellic (cobimetinib) + Zelboraf (vemurafenib), an exception could would be made if the member is intolerant to or has a contraindication to the NCH Preferred Approvable combination. This recommendation policy position is based on a lack of Level 1 evidence to show superiority of one combination of BRAF and MEK inhibitor over another. Please refer to UM ONC_1279 Cotellic (cobimetinib) or UM ONC_1207 Zelboraf (vemurafenib) policy. Please refer to NCH alternative agents/regimens recommended by NCH, including but not limited to regimens available at http://pathways.newcenturyhealth.com.~~ 3. Mekinist (trametinib) may be used in as monotherapy in members in members with unresectable or metastatic BRAF V600E or V600K mutation positive melanoma, if an anti-BRAF targeted therapy was not used previously. A.Solid Tumors with BRAF V600E mutation (excluding colorectal cancer) 1. Mekinist (trametinib) may be used in combination with Tafinlar (dabrafenib) in adult or pediatric members greater than or equal to 6 years of age with unresectable or metastatic solid tumors with BRAF V600E mutation, as subsequent therapy. ~~The use of Mekinist (trametinib) in combination with Tafinlar (dabrafenib) in colorectal cancer is not supported per NCH Policy or NCH Pathway. This recommendation policy position is based on the lack of response to a BRAF inhibitor in RAS wild type colorectal cancer. To overcome this resistance, the recommended alternative therapy for RAS wild type and BRAF V600E mutation positive recurrent/metastatic colorectal cancer is [Erbitux~~	Other: Remove PDL language
Mekinist (trametinib)	Positive change	Remove exclusion criteria: A.The member has BRAF wild-type tumors. ~~The use of Mekinist (trametinib) + Tafinlar (dabrafenib) in colorectal cancer is not supported per NCH policy and NCH pathway.~~ E.Treatment exceeds the maximum limit of 30 (2 mg), ~~60 (1 mg)~~, 120 (0.5 mg) tablets/month.	Per FDA labeling
Tafinlar (dabrafenib)	Negative change	Remove inclusion criteria: B.Melanoma 1.Tafinlar (dabrafenib) may be used in combination with Mekinist (trametinib) as adjuvant treatment, following complete resection, for melanoma with BRAF V600E or V600K mutations OR 2.Tafinlar (dabrafenib) may be used ~~as a single agent or~~ in combination with Mekinist (trametinib) in members with unresectable or metastatic BRAF V600E or V600K mutation positive melanoma and who have intolerance to/contraindication to ~~the use of the preferred MEK and BRAF inhibitor combination,~~ Cotellic (cobimetinib) + Zelboraf vemurafenib).	Per Clinical Trial Analysis/Criteria
Tafinlar (dabrafenib)	Positive change	Remove exclusion criteria: A.The member has wild-type BRAF tumors ~~The use of Tafinlar (dabrafenib) + Mekinist (trametinib) in colorectal cancer is not supported per NCH policy and NCH pathway.~~ B.Disease progression while taking ~~Tafinlar (dabrafenib) or other BRAF inhibitor (e.g., vemurafenib or encorafenib).~~ any MEK inhibitor + BRAF inhibitor combination. E.Treatment exceeds the maximum limit of 180 (50 mg) tablets/month or 120~~60~~ (75 mg) tablets/month.	Per FDA labeling

Gilotrif (afatinib)	Positive change	Add inclusion criteria: B.Non-Small Cell Lung Cancer (NSCLC) 1.Gilotrif (afatinib) may be used as monotherapy in members with advanced /recurrent/metastatic (stage IIIb or IV) NSCLC and ANY of the following: a.As first line therapy in members with EGFR positive mutation (e.g., exon 19 deletions, exon 21 L858R, S768I, L861Q, G719X) that is negative for T790M mutation or Exon 20 insertion mutation OR b.As second line/subsequent therapy following first line treatment with platinum containing chemotherapy, regardless of EGFR mutation status.	Per Compendia Listing
Gilotrif (afatinib)	Negative change	Add exclusion criteria: C.Concurrent use with other anti-cancer therap ies~~y~~.	Per Compendia Listing
Fusilev (levoleucovorin)	Positive change	Remove inclusion criteria: B.Osteosarcoma, Colorectal Cancer, and Overdosages of Folic Acid Antagonists ~~1.NOTE: Per NCH policy, J0642 Khapzory (levoleucovorin) is a non-Preferred drug, except when J9040 Leucovorin and J9041 Levoleucovorin are not available at the office and the drug shortage is reported by the FDA. This recommendation is based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) to support that Khapzory is superior to Leucovorin/Fusilev.~~	Step Therapy Criteria
Fusilev (levoleucovorin)	Positive change	Remove exclusion criteria: C. ~~Treatment in colorectal cancer exceeds the maximum 24 weeks duration limit.~~	Per FDA labeling
Iressa (gefitinib)	Negative change	Remove inclusion criteria: B.Non-Small Cell Lung Cancer (NSCLC) 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 initial ~~or subsequent line~~ therapy.	Per FDA labeling
Iressa (gefitinib)	Negative change	Add exclusion criteria: B.Concurrent use with other anti-cancer therap ies~~y~~. C.Use in members with advanced/metastatic Non-Small Cell Lung Cancer that is positive for the T790M mutation or EGFR Exon 20 insertion mutation.	Per Compendia Listing
Odomzo (sonidegib)	Negative change	Add exclusion criteria: B.Concurrent use with other ~~chemotherapy~~ anticancer therapies. C. Use of Odomzo (sonidegib) for metastatic BCC.	Per FDA labeling
Kymriah (tisagenlecleucel)	No Clinical Changes	N/A	N/A
Aliqopa (copanlisib)	Negative change	Add inclusion criteria: B.Follicular Lymphoma 1.The member has relapsed/refractory indolent Follicular B Cell Lymphoma grades 1-3a and Aliqopa (copanlisib) may be used following disease progression on or after 2 or more prior systemic therapies~~y~~, including an anti-CD20 based regimen (e.g., rituximab +/- CHOP/bendamustine/CVP).	Per FDA labeling
Aliqopa (copanlisib)	Negative change	Add exclusion criteria: B.Concurrent use with other anticancer therap ies~~y~~.	Per FDA labeling
Besponsa (inotuzumab ozogamicin)	Positive change	Add inclusion criteria: B.Acute Lymphoblastic Leukemia (ALL) 1.Besponsa (inotuzumab ozogamicin) may be used as a single agent for Philadelphia chromosome negative or in combination with a tyrosine kinase inhibitor (e.g, imatinib) for Philadelphia chromosome positive relapsed/refractory ~~Philadelphia chromosome negative or positive~~ CD22-positive B cell ALL.	Per FDA labeling

Doptelet (avatrombopag)	Positive change	Remove inclusion criteria: B.Thrombocytopenia in Chronic Liver Disease 1.Doptelet (avatrombopag) may be used as a single agent if the following criteria are satisfied: a.The member has chronic liver disease AND b.A mean baseline platelet count of less than 50 x 109/L AND c.The member is scheduled to undergo an invasive procedure. ~~2.NOTE: Per NCH Policy, Doptelet (avatrombopag) is the preferred agent to increase platelet counts in members with thrombocytopenia associated with chronic liver disease. This recommendation is based on the lack of Level 1 evidence (randomized trial and or meta-analysis) showing superior outcomes with Mulpleta (lusutrombopag) over Doptelet (avatrombopag) for the above clinical setting.~~ C.Idiopathic Thrombocytopenia Purpura (ITP) 1.The member has a diagnosis of relapsed/refractory chronic ITP AND 2.The member has had an insufficient response to (defined by failure of platelet count to increase and stay above 30 x 109/L) or has an intolerance or contraindication to corticosteroids, ~~immunoglobulins (IVIG), AND Rituxan (rituximab)~~ AND 3.Platelet count less than 30,000 109/L prior to start of therapy.	Per FDA labeling
Braftovi (encorafenib)	Positive change	Remove inclusion criteria: C.Melanoma 1.Braftovi (encorafenib) may be used in combination with Mektovi (binimetinib) in BRAF V600E or V600K mutation positive unresectable/metastatic melanoma,and the member has an intolerance/contraindication to ~~the use of the approvable MEK and BRAF inhibitor combination,~~ Cotellic (cobimetinib) + Zelboraf (vemurafenib). ~~2.NOTE: Per NCH Policy, Braftovi (encorafenib) + Mektovi (binimetinib) is Not Approvable for the treatment of metastatic BRAF V600E or V600K mutation positive melanoma. The Approvable oral combination is Zelboraf (vemurafenib) + Cotellic (cobimetinib), an exception could be made if the member is intolerant to or has a contraindication to the approvable combination. This Policy Position is based on a lack of Level 1 evidence to show superiority of one combination of BRAF + MEK inhibitor over another. Please refer to NCH alternative agents/regimens recommended by NCH, including but not limited to regimens available at http://pathways.newcenturyhealth.com.~~	Step Therapy Criteria
Mulpleta (lusutrombopag)	Positive change	Remove inclusion criteria: B.Thrombocytopenia in Chronic Liver Disease 1.Mulpleta (lusutrombopag) may be used ~~in the above setting~~ for thrombocytopenia with chronic liver disease as follows: ~~liver disease~~ if the member has failed/has an intolerance or contraindication to Doptelet (avatrombopag) AND all the following criteria are met: a.The member has chronic liver disease and is scheduled to undergo an elective invasive procedure AND b.Has a platelet count < 50 x 109/L prior to the procedure. 2. ~~NOTE: Per NCH Policy, Mulpleta (lusutrombopag is Not Approvable; Doptelet (avatrombopag) is the preferred Approvable agent for use to increase platelet counts in members with thrombocytopenia associated with chronic liver disease, unless the member has an intolerance or contraindication to Doptelet (avatrombopag). This recommendation policy position is based on the lack of Level 1 evidence (randomized trial and or meta-analysis) showing superior outcomes with Mulpleta (lusutrombopag) over Doptelet (avatrombopag). Please refer to UM ONC_1334 for Doptelet (avatrombopag) policy.~~	Step Therapy Criteria
Mulpleta (lusutrombopag)	Positive change	Remove exclusion criteria: A.Disease progression defined as a lack in rise of Platelet counts, from baseline, after 4 weeks at the maximum tolerated dose AND the member continued to receive platelet ~~blood~~ transfusions while on Mulpleta (lusutrombopag). B. ~~Use after failure with Doptelet (avatrombopag) for thrombocytopenia in chronic liver disease.~~	Step Therapy Criteria

Copiktra (duvelisib)	Positive change	Remove exclusion criteria: A.Disease progression with the same regimen or previous treatment with a PI3K inhibitor [e.g., Zydelig (idelalisib) or Aliqopa (capanlisib)]~~. or BTK inhibitor [e.g., Imbruvica (ibrutinib) or Calquence (acalabrutinib)].~~	Per Clinical Trial Analysis/Criteria
Lumoxiti (moxetumomab pasudotox)	No Clinical Changes	N/A	N/A
Piqray (alpelisib)	Positive change	Remove exclusion criteria: ~~C.Previous therapy with an mTOR inhibitor e.g., Afinitor (everolimus).~~ E.Treatment exceeds the maximum limit of 60 (150 mg), ~~9~~60 (100 mg), or ~~182~~0 (50 mg) tablets/month.	Per FDA labeling
Xpovio (selinexor)	No Clinical Changes	N/A	N/A
Oxbryta (voxelotor)	Negative change	Add exclusion criteria: C.Treatment exceeds the maximum limit of 90 (500 mg) or 90 (300 mg) tablets/month.	Per FDA labeling
Ayvakit (avapritinib)	Positive change	Remove inclusion criteria: B.Gastrointestinal Stromal Tumor (GIST) ~~1.The member has unresectable or metastatic GIST with a documented platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations, and Ayvakit (avapritinib) may be used as monotherapy.~~ ~~1.NOTE: Per NCH Pathway & NCH Policy, Ayvakit (avapritinib) is a non-Preferred drug. Gleevec (imatinib) is the preferred NCH L1 pathway for PDGFRA exon 18 mutation positive (except for D842V mutation) unresectable or metastatic GIST. For PDGFRA D842V mutation positive GIST, Qinlock (ripretinib) is the preferred treatment over Ayvakit (avapritinib) in this setting.~~ ~~a.Rationale: Ayvakit was FDA approved via phase 1 study and the primary outcome was ORR. The INVICTUS trial demonstrated improved OS for Qinlock (ripretinib), 15 months versus 6 months (HR 0.36, 95% CI 0.20-0.62) and PFS benefit, 6 versus 1 month (HR 0.15, 95% CI 0.09-0.25) relative to placebo.1 Please refer to UM ONC_1177 Gleevec (imatinib mesylate) and UM ONC_1404 Qinlock (ripretinib) policies, respectively.~~ 1.The member has unresectable or metastatic GIST with a documented PDGFRA D842V mutation OR 2.The member has a documented platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation and has received prior therapy with generic imatinib for the treatment of unresectable or metastatic GIST, unless there is an intolerance/contraindication to generic imatinib. The above policy position is based on the lack of Level 1 Evidence (randomized clinical trials and/or meta-analyses) to show superior outcomes with Ayvakit (avapritinib) compared to generic imatinib or NCH recommended alternatives agents/regimens, including but not limited to regimens at http://pathways.newcenturyhealth.com.	Step Therapy Criteria
Mektovi (binimetinib)	Positive change	Remove inclusion criteria: B.Melanoma 1.The member has metastatic/unresectable melanoma with BRAF V600E or V600K activating mutation AND 2.Mektovi (binimetinib) will be used in combination with Braftovi (encorafenib) AND 3.The member is intolerant to/has a contraindication to ~~the approvable combination of~~ Cotellic (cobimetinib) + Zelboraf (vemurafenib). ~~4.NOTE: Per NCH Policy, Mektovi (binimetinib) + Braftovi (encorafenib) regimen is Not Approvable for the treatment of metastatic BRAF V600E or V600K mutation positive melanoma. The Approvable oral combination is Cotellic (cobimetinib) + Zelboraf (vemurafenib), an exception could be made if the member is intolerant to or has a contraindication to the approvable combination. This Policy Position is based on a lack of Level 1 evidence to show superiority of one combination of BRAF and MEK inhibitor over another. Please refer to NCH alternative agents/regimens recommended by NCH, including but not limited to regimens available at http://pathways.newcenturyhealth.com.~~	Step Therapy Criteria

Inqovi (decitabine and cedazuridine)	Negative change	Add inclusion criteria: B.Myelodysplastic Syndromes (MDS) 1.The member has MDS and Inqovi may be used as an oral fixed dose combination therapy (decitabine 35 mg and cedazuridine 100 mg) only when there is documented confirmation of a contraindication/intolerance to Vidaza (azacitdine) or Dacogen (decitabine). ~~2.NOTE: Per NCH Policy and NCH Pathway, Inqovi (decitabine and cedazuridine) is a non- preferred drug for the treatment of MDS. The preferred agents are Vidaza (azacitidine) and Dacogen (decitabine). This position is based on the lack of Level 1 evidence (randomized phase III trials and or meta-analyses) to show superior outcomes (any of the following: a. Progression Free Survival, b. Overall Survival, c. Time to progression to Acute Leukemia) with Inqovi over Vidaza or Dacogen .~~	Step Therapy Criteria
Onureg (azacitidine oral)	Positive change	Remove inclusion criteria: B.Acute Myeloid Leukemia 1.Onureg (azacitidine oral) may be used as a single agent as maintenance therapy in a members with AML in first complete remission following induction therapy who are unable to receive or are considered clinically unsuitable to receive ~~3 or more cycles of~~ consolidation therapy after induction and achievement of CR (e.g., HIDAC consolidation). ~~This recommendation policy position 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).~~	Per Clinical Trial Analysis/Criteria
Onureg (azacitidine oral)	Negative change	Add exclusion criteria: ~~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.~~ A.Use of Onureg (azacitidine oral) as a substitute for intravenous Vidaza (azacitidine)/Dacogen (decitabine) for the treatment of MDS. B.Use of Onureg in patient who have completed 3 or more cycles of Cytarabine-based consolidation therapy after achieving a complete remssion with induction therapy (e.g., High Dose Ara-C x 3 or more cycles).	Per Clinical Trial Analysis/Criteria

Topical and Intralesional Therapies	Negative change	B.Basal Cell Carcinoma (BCC) e.Note: Per NCH policy, Levulan Kerastick, Carac, and Fluoroplex are Not Approvable for the topical treatment of primary or recurrent low risk BCC. Efudex (topical fluorouracil) and Aldara (topical imiquimod) are the ~~preferred~~ Approvable treatment options over other topical/intralesional therapies for the treatment of BCC. This ~~recommendation~~ policy position is based on the lack of level 1 evidence (randomized trial and/or meta-analysis) to show superior outcomes with other topical therapies (e.g., Carac, Fluroplex, Levulan Kerastick) over Efudex (topical fluorouracil) and Aldara (topical imiquimod). C.Cutaneous Squamous Cell Carcinoma (cSCC) 3.The following may be used as monotherapy, or as combination therapy following the failure of monotherapy, for the topical/intralesional treatment of primary or recurrent low risk cSCC in members who are not candidates for surgery and/or radiation therapy: a.Levulan Kerastick (aminolevulinic acid hydrochloride): for use as photodynamic therapy for superficial cSCC. a.b.Carac, Efudex, or Fluoroplex (topical fluorouracil): for use as topical therapy for actinic keratoses OR for cSCC in situ (Bowen's disease). b.c.Aldara (topical imiquimod): for use as topical therapy for actinic keratoses OR for cSCC in situ (Bowen's disease). d.Klisyri (topical tirbanibulin): topical therapy for actinic keratoses. c.e.The use of intralesional therapies as palliative treatment of low risk cSCC, when all alternate treatment modalities have failed or are not possible, may include the following: fluorouracil (5FU), methotrexate (MTX), bleomycin, and interferon (IFN alfa 2a/2b, beta, and gamma). Unlike topical therapies, this recommendation is derived from small retrospective case series and are not supported by robust study design, study size, and long term follow up and cure rate data. Please refer to attachment C for details on dose and administration. d.f.NOTE: Per NCH policy, Levulan Kerastick, Carac Fluoroplex, and Klisyri are Not Approvable for the topical treatment of primary or recurrent low risk cSCC. Efudex (topical fluorouracil) and Aldara	More Cost Effective Alternative(s)
Fyarro (intravenous sirolimus)	No Clinical Changes	N/A	N/A
Vonjo (pacritinib)	Positive change	Remove inclusion criteria: B.Myelofibrosis (MF) 1.The member has intermediate or high-risk primary or secondary myelofibrosis (post-polycythemia vera or post-essential thrombocythemia) with thrombocytopenia as defined by a platelet count below 50 × 109/L, either at baseline or after therapy with another JAK inhibitor [e.g. Jakafi (ruxolitinib)] AND ~~1.The member has splenomegaly AND~~ ~~2.Intermediate (2 prognostic factors) or high-risk (3 or more prognostic factors) myelofibrosis is defined by the following:~~ ~~a.Age > 65 years~~ ~~b.Hemoglobin < 10 g/dL~~ ~~c.Leukocytes > 25 x 109//L~~ ~~d.Circulating blasts ≥ 1%~~ ~~e.Platelet count < 100 x 109/L~~ ~~f.RBC transfusion need~~ ~~g.Unfavorable karyotype +8, -7/7q-, i(17q), inv(3), -5/5q-, 12p-, 11q23.~~	Per Clinical Trial Analysis/Criteria
Vonjo (pacritinib)	Positive change	Remove exclusion criteria: B. ~~Concurrent use with other erythropoietic (e.g., epoetin or darbepoetin) or thrombopoietic agent (e.g., anagrelide, aspirin) .~~	Per FDA labeling
Pluvicto (lutetium Lu 177 vipivotide tetraxetan)	Negative change	Add inclusion criteria: B.Prostate Cancer 1.Pluvicto (lutetium Lu 177 vipivotide tetraxetan) may be used as monotherapy in members with prostate-specific membrane antigen (PSMA) positive (confirmed on a PSMA PET/CT scan) ~~for~~ metastatic castration-resistant prostate cancer following disease progression on or after 2 prior lines of therapy including an Androgen Receptor Pathway Inhibitor (e.g., enzalutamide, abiraterone) AND a taxane-based chemotherapy (e.g., docetaxel).	Per FDA labeling

Pluvicto (lutetium Lu 177 vipivotide tetraxetan)	Negative change	Add exclusion criteria: B.Concurrent use with other cytotoxic chemotherapy, immunotherapy, or radioligand therapy.	Per Clinical Trial Analysis/Criteria