PROVIDER NOTIFICATION OF POLICY CRITERIA CHANGE					
POLICY TITLE	**POLICY NUMBER**	**CRITERIA CHANGE**	**MATERIAL AMENDEMENT**	**EFFECTIVE DATE**	**LINK TO FULL POLICY**
Mirvetuximab soravtansine-gynx (e.g. Elahere)	2023019	FDA and off-label authorization renewal criteria updated. FDA Labeled Indications: AUTHORIZATION RENEWAL: 1. Condition stable or improved with treatment; AND 2. Manageable or no side effects; AND 3. Individual will be using mirvetuximab soravtansine-gynx as a single agent (Matulonis, 2023). 4. Individual has an ECOG performance status of 0-1* (Matulonis, 2023). Off-Label Indications: AUTHORIZATION RENEWAL: 1. Condition stable or improved with treatment; AND 2. Manageable or no side effects.	No	July 13, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2023019
Goserelin (e.g., Zoladex)	2024081	FDA and off-label authorization renewal criteria updated. FDA Labeled Indications: AUTHORIZATION RENEWAL: 1. Condition stable or improved with treatment; AND 2. Manageable or no side effects. Off-Label Indications: AUTHORIZATION RENEWAL: 1. Condition stable or improved with treatment; AND	No	July 13, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2024081

		2. Manageable or no side effects. Off-label indications updated. 1. Head and Neck Cancers – Salivary Gland tumors (NCCN 2A); OR 2. Prostate Cancer (NCCN 1 and 2A); OR 3. Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer: a. Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer (NCCN 2A); OR b. Carcinosarcoma or Malignant Mixed Mullerian Tumors (NCCN 2A); OR c. Clear Cell Carcinoma of the Ovary (NCCN 2A); OR d. Mucinous Neoplasms of the Ovary (NCCN 2A); OR e. Grade 1 Endometrioid Carcinoma (NCCN 2A); OR f. Low-Grade Serous Carcinoma (NCCN 2A); OR g. Malignant Sex Cord-Stromal Tumors (NCCN 2A); OR 4. Breast Cancer: a. Invasive Breast Cancer (NCCN 1 and 2A); OR b. Inflammatory Breast Cancer (NCCN 1 and 2A); OR 5. Uterine Neoplasms - Uterine Sarcoma (NCCN 2A)			
Ramucirumab (e.g., Cyramza)	2017016	FDA and off-label authorization renewal criteria updated. FDA Labeled Indications: AUTHORIZATION RENEWAL: 1. Condition stable or improved with treatment; AND 2. Manageable or no side effects. Off-Label Indications:	No	July 13, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2017016

		AUTHORIZATION RENEWAL: 1. Condition stable or improved with treatment; AND 2. Manageable or no side effects. Off-label indications updated. **1.** Thymomas and Thymic Carcinomas: a. In combination with carboplatin and paclitaxel for consideration as preoperative* systemic therapy for surgically resectable disease if R0 resection is considered uncertain (for thymic carcinoma only) (NCCN 2A); OR b. Preferred postoperative treatment in combination with carboplatin and paclitaxel for thymic carcinoma after R1 or R2 resection(NCCN 2A); OR c. Preferred first-line therapy for recurrent, advanced, or metastatic disease in combination with carboplatin and paclitaxel (for thymic carcinoma only) for (NCCN 2A): i. Potentially resectable locally advanced disease; OR ii. Potentially resect able solitary metastasis or ipsilateral pleural metastasis; OR iii. Consideration following surgery for solitary metastasis or ipsilateral pleural metastasis; OR iv. Medically inoperable/unresectable solitary metastasis or ipsilateral pleural metastasis; OR v. Extrathoracic metastatic disease; OR 2. Mesothelioma: Pleural: a. Subsequent systemic therapy in combination with gemcitabine (NCCN 2A); OR 3. Non-Small Cell Lung Cancer: a. Subsequent systemic therapy (first progression after initial systemic			

		therapy) in combination with docetaxel (if not already given) for recurrent, advanced, or metastatic disease in individuals with performance status 0-2 (NCCN 2A); OR 4. Gastric Cancer: a. Palliative therapy for locoregional disease (Gastric Cancer) in individuals who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic disease (including peritoneal only metastatic disease, including positive cytology) and Karnofsky performance score greater than or equal to 60% or ECOG performance score less than or equal to 2 as second-line or subsequent therapy in combination with irinotecan with or without fluorouracil, in combination with paclitaxel (preferred) or as a single agent (NCCN 2A for combination with irinotecan with or without fluorouracil; NCCN 1 for all others); OR 5. Esophageal and Esophagogastric Junction Cancers: a. Palliative therapy for individuals who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic adenocarcinoma and Karnofsky performance score greater than or equal to 60% or ECOG performance score less than or equal to 2 in combination with irinotecan with or without fluorouracil ion with paclitaxel (preferred) or as a single agent (NCCN 1 for combination with paclitaxel for EGJ adenocarcinoma; NCCN 2A for all others); OR 6. Colon Cancer: a. Colon Cancer:			

		i. Initial treatment for individuals with unresectable metachronous metastases (i.e., occurrence after a period of 3 months postoperatively) and previous adjuvant fluorouracil, leucovorin, and irinotecan (e.g., FOLFIRI) or capecitabine and oxaliplatin (e.g., CAPEOX) within the past 12 months (NCCN 2A): 1. In combination with irinotecan; OR 2. In combination with fluorouracil, leucovorin, and irinotecan (e.g., FOLFIRI) regimen; OR ii. Second-line and subsequent therapy for progression of advanced or metastatic disease (proficient mismatch repair/microsatellite-stable [pMMR/MSS] or ineligible for or progressed on checkpoint inhibitor immunotherapy for deficient mismatch repair/microsatellite instability-high [dMMR/MSI-H] or polymerase epsilon/delta [POLE/POLD1] mutation with ultra-hypermutated phenotype [eg, TMB greater than 50 mut/Mb]), in combination with irinotecan or with fluorouracil, leucovorin, and irinotecan (FOLFIRI) regimen, if not previously given, in			

		individuals not previously treated with irinotecan-based therapy (NCCN 2A); OR iii. Second-line and subsequent therapy for progression of advanced or metastatic disease in combination with irinotecan or with fluorouracil, leucovorin, and irinotecan (FOLFIRI) regimen, if not previously given and if not previously treated with irinotecan-based therapy or not previously treated with oxaliplatin or irinotecan (NCCN 2A); OR 7. Rectal Cancer: a. Initial treatment for individuals with unresectable metachronous metastases [pMMR/MSS] or deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) or polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype (e.g., TMB greater than 50 mut/Mb) and are not candidates for immunotherapy) and previous adjuvant fluorouracil, leucovorin, and oxaliplatin (e.g., FOLFOX) or capecitabine and oxaliplatin (e.g., CAPEOX) within the past 12 months (NCCN 2A): i. In combination with irinotecan; OR ii. In combination with fluorouracil, leucovorin, and irinotecan (e.g., FOLFIRI) regimen; OR b. Second-line and subsequent therapy for progression of advanced or metastatic disease in combination with irinotecan or with fluorouracil, leucovorin, and			

		irinotecan (FOLFIRI) regimen, if not previously given, in individuals not previously treated with irinotecan-based therapy or ineligible for or progressed on checkpoint inhibitor immunotherapy for deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) or polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype (e.g., TMB greater than 50 mut/Mb) (NCCN 2A); **OR** 8. Hepatocellular Carcinoma: a. Subsequent-line systemic therapy as a single agent if progression on or after systemic therapy and AFP greater than or equal to 400 ng/mL (NCCN 1)			
Daratumumab (e.g., Darzalex) / Daratumumab and Hyaluronidase-fihj (e.g., Darzalex Faspro)	2016012	DARATUMUMAB (E.G., DARZALEX) FDA and off-label criteria updated for initial and authorization renewal. FDA Approved Indications: <u>MULTIPLE MYELOMA</u> INITIAL APPROVAL: 1. Individual is 18 years of age or older (Darzalex, 2025); AND 2. Individual has a diagnosis of multiple myeloma; AND 3. Daratumumab (e.g., Darzalex) will be used: a. In combination with lenalidomide and dexamethasone in newly diagnosed individuals who are ineligible for autologous stem cell transplant and in individuals with relapsed or refractory multiple myeloma who have received at least one prior therapy (Darzalex, 2025); OR	No	July 13, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2016012

		b. In combination with bortezomib, melphalan and prednisone in newly diagnosed individuals who are ineligible for autologous stem cell transplant (Darzalex, 2025); OR c. In combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed individuals who are eligible for autologous stem cell transplant (Darzalex, 2025); OR d. In combination with bortezomib and dexamethasone in individuals who have received at least one prior therapy (Darzalex, 2025); OR e. In combination with carfilzomib and dexamethasone in individuals with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy (Darzalex, 2025); OR f. In combination with pomalidomide and dexamethasone in individuals who have received at least one prior therapies including lenalidomide and a proteasome inhibitor (Darzalex, 2025; NCCN 1); OR g. As monotherapy, in individuals who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent (Darzalex, 2025; NCCN 2A). AUTHORIZATION RENEWAL: 1. Condition stable or improved with treatment; AND 2. Manageable or no side effects. <u>Off-Label Indications:</u> INITIAL APPROVAL:			

		1. Multiple Myeloma: a. Primary therapy for symptomatic multiple myeloma for transplant candidates: i. In combination with bortezomib, lenalidomide, and dexamethasone (NCCN 1); OR ii. In combination with carfilzomib, lenalidomide, and dexamethasone (NCCN 2A); OR b. Primary therapy for symptomatic multiple myeloma or for disease relapse after 6 months following primary induction therapy with the same regimen: iii. In combination with lenalidomide and dexamethasone for non-transplant candidates (NCCN 1); OR iv. In combination with cyclophosphamide, bortezomib, and dexamethasone (useful in certain circumstances when used as primary therapy; other recommended regimen when used in the relapse setting) (NCCN 2A); OR c. Maintenance therapy for symptomatic multiple myeloma in combination with lenalidomide (two-drug maintenance is recommended for high-risk disease) for transplant candidates: v. After response to primary myeloma therapy (NCCN 2A); OR vi. For response or stable disease following an autologous hematopoietic cell transplant (HCT) (NCCN 1); OR			

		vii. For response or stable disease following a tandem autologous or allogeneic HCT for high-risk individuals under certain circumstances (NCCN 2A); OR d. Therapy for previously treated multiple myeloma for relapse or for progressive disease: i. In combination with dexamethasone and bortezomib if lenalidomide-refractory (NCCN 1); OR ii. In combination with carfilzomib and dexamethasone if bortezomib- or lenalidomide-refractory (NCCN 1); OR iii. In combination with dexamethasone and lenalidomide if bortezomib-refractory (NCCN 1); OR iv. In combination with pomalidomide and dexamethasone in individuals who have received one prior therapy including lenalidomide and a proteasome inhibitor (NCCN 1); OR v. In combination with cyclophosphamide, bortezomib, and dexamethasone; OR vi. In combination with carfilzomib, pomalidomide, and dexamethasone; OR vii. As a single agent in individuals who have received at least three			

		prior therapies, including a proteasome inhibitor and an immunomodulatory agent, or who are double refractory to a proteasome inhibitor and an immunomodulatory agent (NCCN 2A); OR viii. In combination with selinexor and dexamethasone (NCCN 2A); OR ix. Combination with venetoclax and dexamethasone for individuals with t(11:14) (NCCN 2A); OR e. Treatment in combination with lenalidomide and dexamethasone for the management of POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome as induction therapy for transplant eligible individuals (NCCN 2A); OR 2. Systemic Light Chain Amyloidosis: a. Treatment for relapsed/refractory disease as a single agent (NCCN 2A): i. As a single agent; OR ii. In combination with lenalidomide and dexamethasone; OR b. Treatment for newly diagnosed disease or consider for relapsed/refractory disease as a repeat of initial therapy if relapse-free for several years (NCCN 1 for combination with bortezomib, cyclophosphamide and dexamethasone for new diagnosed stage I-IIIa disease if no significant neuropathy; 2A for all others): i. In combination with bortezomib,			

		cyclophosphamide, and dexamethasone for stage I-IIIa if no significant neuropathy; OR ii. As part of dose-modified daratumumab, cyclophosphamide, bortezomib and dexamethasone regimen for stage IIIb if no significant neuropathy; OR iii. As a single agent for stage IIIb if no significant neuropathy; OR iv. In combination with bortezomib, cyclophosphamide, and dexamethasone for all stages if significant neuropathy; OR 3. Pediatric Acute Lymphoblastic Leukemia: a. Therapy for relapsed/refractory T-ALL as a component of daratumumab-containing regimen (daratumumab, vincristine, pegaspargase or calaspargase, doxorubicin, and prednisone or dexamethasone) (NCCN 2A); OR 4. B-Cell Lymphomas: a. Preferred first-line therapy for HIV-related plasmablastic lymphoma as a component of dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, and doxorubicin) with daratumumab regiment. (NCCN 2A) AUTHORIZATION RENEWAL: 1. Condition stable or improved with treatment; AND 2. Manageable or no side effects.			

		DARATUMUMAB AND HYALURONIDASE-FIHJ (E.G., DARZALEX FASPRO) FDA and off-label criteria updated for initial and authorization renewal. <u>MULTIPLE MYELOMA</u> INITIAL APPROVAL: 1. Individual is 18 years of age or older (Darzalex Faspro, 2026); AND 2. Individual has a diagnosis of multiple myeloma; AND 3. Daratumumab and Hyaluronidase-fihj (e.g., Darzalex Faspro) will be used: a. In combination with bortezomib, lenalidomide, and dexamethasone for induction and consolidation in newly diagnosed individuals who are eligible for autologous stem cell transplant (Darzalex Faspro, 2026); OR b. In combination with bortezomib, melphalan and prednisone in newly diagnosed individuals. who are ineligible for autologous stem cell transplant (Darzalex Faspro, 2026); OR c. In combination with lenalidomide and dexamethasone in newly diagnosed individuals. who are ineligible for autologous stem cell transplant and in individuals. with relapsed or refractory multiple myeloma who have received at least one prior therapy (Darzalex Faspro, 2026); OR d. In combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed individuals. who are eligible for autologous stem cell transplant (Darzalex Faspro, 2026); OR e. In combination with bortezomib and dexamethasone in individuals who			

		have received at least one prior therapy (Darzalex Faspro, 2026); OR f. In combination with pomalidomide and dexamethasone in individuals who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor (Darzalex Faspro, 2026); OR g. In combination with carfilzomib and dexamethasone in individuals with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy (Darzalex Faspro, 2026); OR h. As monotherapy, in individuals who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent (Darzalex Faspro, 2026); OR i. As monotherapy in individuals with high-risk smoldering multiple myeloma (Darzalex Faspro, 2026); OR j. In combination with teclistamab in individuals who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent (Tecvayli, 2026) AUTHORIZATION RENEWAL: 1. Condition stable or improved with treatment; AND 2. Manageable or no side effects. <u>SYSTEMIC LIGHT CHAIN AMYLOIDOSIS</u> INITIAL APPROVAL:			

		1. In combination with bortezomib, cyclophosphamide, and dexamethasone in newly diagnosed individuals. (Darzalex Faspro, 2024). AUTHORIZATION RENEWAL: 1. Condition stable or improved with treatment; AND 2. Manageable or no side effects. <u>Off-Label Indications</u> INITIAL APPROVAL: 1. Multiple Myeloma: a. Therapy for previously treated multiple myeloma for relapse or for progressive disease in combination with teclistamab-cqyv if bortezomib or lenalidomide refractory (NCCN 1); OR b. Primary therapy for symptomatic multiple myeloma in combination with bortezomib, lenalidomide, and dexamethasone if transplant-deferred or is transplant not indicated in individuals less than 80 years old who are not frail (NCCN 1); OR c. As a single agent or in combination with other systemic therapies where intravenous daratumumab is recommended (NCCN 2A); OR 2. Systemic Light Chain Amyloidosis: a. May be substituted for intravenous daratumumab (NCCN 2A). AUTHORIZATION RENEWAL: 1. Condition stable or improved with treatment; AND 2. Manageable or no side effects.			