PROVIDER NOTIFICATION OF POLICY CRITERIA CHANGE					
POLICY TITLE	**POLICY NUMBER**	**CRITERIA CHANGE**	**MATERIAL AMENDEMENT**	**EFFECTIVE DATE**	**LINK TO FULL POLICY**
Levodopa-carbidopa Intestinal Gel (e.g., Duopa) for Treatment of Advanced Parkinson's Disease	2018023	FDA label initial and authorization renewal criteria added. Per prescribing label, vitamin B6 levels should be evaluated prior to initiating carbidopa/levodopa therapies periodically during treatment, and as clinically indicated. **Click the following link to view the InterQual® criteria:** https://prod.ds.interqual.com/service/connect/transparency?tid=27b0a724-ca06-4b22-846b-598b8dae52fc	no	September 17, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2018023
Nadofaragene firadenovec-vncg (e.g., Adstiladrin)	2023020	Off-label initial approval and authorization criteria added. Off-label Indications The use of this drug for off-label indications not listed below is subject to policy 2000030. INITIAL APPROVAL: 1. Individual has a diagnosis of high-risk non-muscle invasive bladder cancer (NMIBC) with either carcinoma in situ (CIS) with or without Ta/T1 papillary tumors or Ta/T1 papillary tumors without CIS (NCCN 2A): a. As initial management; OR b. For cytology-positive, imaging and cystoscopy-negative, bladder positive recurrent or persistent disease. AUTHORIZATION RENEWAL: 1. Condition improved with treatment; AND 2. Manageable or no side effects with treatment; AND 3. Individual will be using nadofaragene firadenovec-vncg as a single agent (Boorjian, 2019); AND	no	September 17, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2023020

		4. Individual has an ECOG performance status of 0-2* (Boorjian, 2019).			
Nipocalimab (e.g., Imaavy)	2025029	Coverage criteria updated. 5. Individual has inadequate treatment response, intolerance, or contraindication to an acetylcholinesterase inhibitor (e.g., pyridostigmine) (Bird, 2024) AND meets one of the following: a. Individual has inadequate treatment response to a 6-month trial with at least one or more of the following immunosuppressants: Azathioprine, Cyclosporine, Mycophenolate mofetil, Tacrolimus, Glucocorticoids, Methotrexate, Cyclophosphamide; OR b. Individual has a documented intolerance or contraindication to all listed immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, glucocorticoids, methotrexate, or cyclophosphamide); OR c. Individual is on a stable dose of one or more immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, glucocorticoids, methotrexate, or cyclophosphamide) and has required four or more rescue or bridge therapies [e.g., intravenous immune globulin (IVIG) or therapeutic plasma exchange] within 12 months (Alhaidar, 2022). **Click the following link to view the InterQual® criteria:** https://prod.ds.interqual.com/service/connect/transparency?tid=27b0a724-ca06-4b22-846b-598b8dae52fc	no	September 17, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2025029
Efgartigimod (e.g., Vyvgart)	2022001	FDA label criteria updated. Removed Acetylcholine receptor positivity requirement. **Click the following link to view the InterQual® criteria:** https://prod.ds.interqual.com/service/conne	no	September 17, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2022001

		ct/transparency?tid=27b0a724-ca06-4b22-846b-598b8dae52fc			
Efgartigimod alfa and Hyaluronidase-qvfc (e.g., Vyvgart Hytrulo)	2024063	FDA label criteria updated. Removed Acetylcholine receptor positivity requirement. **Click the following link to view the InterQual® criteria:** https://prod.ds.interqual.com/service/connect/transparency?tid=27b0a724-ca06-4b22-846b-598b8dae52fc	no	September 17, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2024063
White Blood Cell Growth Factors	2021024	Preferred/Non-Preferred Products list updated. Preferred Products: HCPCS, Brand Name, Generic Name Q5108, Fulphila, Pegfilgrastim-jmdb J2506, Neulasta, Pegfilgrastim J2506, Neulasta OnPro, Pegfilgrastim Q5110, Nivestym, Filgrastim-aafi Q5101, Zarxio, Filgrastim-sndz Non-Preferred Products: HCPCS, Brand Name, Generic Name Q5130, Fylnetra, Pegfilgrastim-pbbk J1447, Granix, Tbo-filgrastim J2820, Leukine, Sargramostim J1442, Neupogen, Filgrastim Q5148, Nypozi, Filgrastim-txid Q5122, Nyvepria, Pegfilgrastim-apgf Q5125, Releuko, Filgrastim-ayow J1449, Rolvedon, Eflapegrastim-xnst J9361, Ryzneuta, Efbemalenograstim alfa-vuxw Q5127, Stimufend, Pegfilgrastim-fpgk Q5111, Udenyca, Pegfilgrastim-cbqv Q5111, Undenyca Onbody, Pegfilgrastim-cbqv Q5120, Ziextenzo, Pegfilgrastim-bmez Q5169, Armlupeg, Pegfilgrastim-unne (active 7/1/2026) J3590, Filkri, Filgrastim-laha (active 6/1/2026) Clinical criteria updated for Oncologic Use of White Blood Cell Colony Stimulating Factors (WBC CSFs).	no	September 17, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2021024

		PRIMARY PROPHYLAXIS OF FEBRILE NEUTROPENIA (Any agent preferred, except sargramostim) Note: Consideration should be given to equally effective and safe alternative chemotherapy treatment options that do not require CSF support, when available. Note: CSFs are not recommended for individuals receiving combined chemoradiotherapy, particularly when involving the mediastinum, and there is little evidence to support the use of CSFs in patients receiving radiation therapy alone. One white blood cell (WBC) growth factor agent is considered clinically appropriate for primary prophylaxis of chemotherapy-induced febrile neutropenia when ALL the following (1, 2, and 3) are met: 1. The individual has a non-myeloid malignancy; AND 2. Chemotherapy intent must include one of the following: a. Curative intent (adjuvant treatment for early-stage disease, for example); OR b. Intent is survival prolongation, and the use of a different regimen or dose reduction would reduce the likelihood of reaching the treatment goal; OR c. Intent is symptom management, and the use of a different regimen or dose reduction would reduce the likelihood of reaching the treatment goal; AND 3. The individual falls into one of the following clinically significant risk categories for febrile neutropenia (FN) per Carelon MBM Appropriate Use Criteria for Febrile Neutropenia Risk: https://guidelines.carelonmedicalbenefitsmanagement.com/febrile-neutropenia-			

		risk/Febrile-Neutropenia-Risk-2025-11-15.pdf a. High risk of febrile neutropenia (greater than or equal to 20%) based on chemotherapy regimen; OR b. Intermediate risk of febrile neutropenia (greater than or equal to 10% but (less than 20%) based on chemotherapy regimen, and at least ONE of the following significant risk factors: i. Age 65 years of age or older OR frailty (based on geriatric assessment); OR ii. Poor performance status (ECOG 3 or 4, but chemotherapy still indicated) (Lyman 2014); OR iii. Preexisting neutropenia, for example resulting from bone marrow damage or tumor infiltration (ANC less than 1500 mm to the 3rd power) (Lyman 2014); OR iv. Previous febrile neutropenia episode; OR v. Liver dysfunction, with bilirubin greater than or equal to 1.0 or liver enzymes greater than or equal to 2x upper limit of normal; OR vi. Presence of open wounds or active infections when chemotherapy cannot be delayed to accommodate recovery; OR vii. Renal dysfunction with creatinine clearance of less than 50 mL/min (Lyman 2014) (Aagaard 2018); OR viii. Poor nutritional status (baseline albumin less than			

		or equal to 3.5 g/dL or BMI less than 20); OR ix. HIV infection (active) requiring ongoing antiviral therapy (Lyman 2014); OR x. High tumor volume and/or high symptom burden from disseminated or unresectable malignancy; OR xi. Multiple serious comorbid conditions in addition to the malignancy being treated. SECONDARY PROPHYLAXIS OF FEBRILE NEUTROPENIA (Filgrastim and biosimilars, pegfilgrastim and biosimilars, tbo-filgrastim) Secondary prophylaxis of febrile neutropenia is considered clinically appropriate when there has been a previous neutropenic complication (in the absence of primary prophylaxis), and a change to the regimen (including dose reduction, schedule change, or change in therapy) would be expected to compromise individual outcome, particularly in the setting of curative intent. ADJUNCTIVE TREATMENT OF FEBRILE NEUTROPENIA(primary prophylaxis not given Filgrastim and biosimilars, pegfilgrastim and biosimilars, tbo-filgrastim Adjunctive treatment of febrile neutropenia is considered clinically appropriate when ANY of the following risk factors are present: 1. Age 65 years of age or older OR frailty (based on geriatric assessment); OR 2. Neutrophil recovery is expected to be delayed (greater than 7 days); OR 3. Neutropenia is profound (less than 0.1 x 10 to the 9th power); OR 4. Active pneumonia; OR 5. Sepsis syndrome (hypotension and/or multi-organ damage/dysfunction noted); OR 6. Invasive fungal or opportunistic infection; OR 7. Onset of fever during inpatient stay.			

		Note: Febrile neutropenia (FN) is defined as an oral temperature greater than 38.3°C (101.0°F) or 2 consecutive readings of 38.0°C (100.4°F) for 1 hour, with an absolute neutrophil count less than 500 cells/microL (0.5 x 10 to the 9th power/L) or less than 1000 cells/microL and expected to fall below 500 cells/microL over the next 48 hours. The use of multiple WBC growth factor agents for prophylaxis and/or adjunctive treatment within a given chemotherapy cycle is NOT clinically indicated. OTHER ONCOLOGIC USES FOR WBC GROWTH FACTORS The following indications by growth factor type are also considered clinically appropriate if the requirements below are met: Filgrastim and biosimilars (G-CSF) 1. Acute lymphocytic leukemia (ALL): a. After start of induction or first post-remission chemotherapy course; OR b. As an alternate or adjunct to donor leukocyte infusions (DLI) for relapsed disease after transplant; OR 2. Acute myeloid leukemia (AML): a. After induction, reinduction, or consolidation; OR b. As an alternate or adjunct to donor leukocyte infusions (DLI) for relapsed disease after transplant; OR 3. Aplastic anemia, moderate or severe; OR 4. Hairy cell leukemia (NCCN): a. To treat severe neutropenia; OR 5. Hematopoietic stem cell transplant: a. To promote bone marrow myeloid recovery; OR b. To treat delayed or failed engraftment; OR c. To mobilize stem cells for collection by pheresis; OR			

		6. Myelodysplastic syndrome (MDS): a. To treat recurrent infection; OR b. To treat neutrophil count less than 500 cubed millimeters; OR c. MDS: Treatment of lower risk disease [(defined as IPSS-R (Very Low, Low, Intermediate), IPSS (Low/Intermediate-1), WPSS (Very Low, Low, Intermediate)] associated with symptomatic anemia, without del(5q), with or without other cytogenetic abnormalities, with serum erythropoietin less than or equal to 500 mU/mL and either of the following: i. Ring sideroblasts greater than 15% in combination with an erythropoiesis-stimulating agent (ESA); OR ii. Ring sideroblasts less than 15% in combination with lenalidomide and an ESA following no response (despite adequate iron stores) or loss of response to an ESA alone; OR 7. Radiation exposure: a. Following radiation therapy in the absence of chemotherapy if prolonged delays are expected; OR b. After accidental or intentional body irradiation of doses greater than 2 Gy (hematopoietic syndrome of acute radiation syndrome, H-ARS); OR 8. Support for dose dense or dose intensive chemotherapy in any of the following scenarios: a. Adjuvant treatment of high-risk breast cancer with combination therapy that includes anthracycline (doxorubicin or epirubicin)/cyclophosphamide followed by paclitaxel; OR			

		b. High-dose intensity methotrexate, vinblastine, doxorubicin, and cisplatin (HD-M-VAC) in urothelial cancer; OR c. Chemotherapy intensification for newly diagnosed localized Ewing sarcoma. Pegfilgrastim and biosimilars (G-CSF) 1. Acute lymphocytic leukemia (ALL): a. After start of induction or first post-remission chemotherapy course; OR 2. Hematopoietic stem cell transplant: a. To promote bone marrow myeloid recovery; OR b. To treat delayed or failed engraftment; OR 3. Myelodysplastic syndrome (MDS): a. To treat recurrent infection; OR b. To treat neutrophil count less than 500 cubed millimeters; OR 4. Radiation exposure: a. After accidental or intentional body irradiation of doses greater than 2 Gy; OR 5. Support for dose dense chemotherapy in any of the following scenarios: a. Adjuvant treatment of high-risk breast cancer with combination therapy that includes anthracycline (doxorubicin or epirubicin)/cyclophosphamide followed by paclitaxel; OR b. High-dose intensity methotrexate, vinblastine, doxorubicin, and cisplatin (HD-M-VAC) in urothelial cancer; OR c. Chemotherapy intensification for newly diagnosed localized Ewing sarcoma. Sargramostim 1. Acute lymphocytic leukemia (ALL):			

		a. After start of induction or first post-remission chemotherapy course; OR 2. Acute myeloid leukemia (AML): a. After induction, reinduction, for individuals over 55 years of age; OR 3. Hematopoietic stem cell transplant: a. To promote bone marrow myeloid recovery; OR b. To treat delayed or failed engraftment; OR c. To mobilize stem cells for collection by pheresis; OR 4. Myelodysplastic syndrome (MDS): a. To treat recurrent infection; OR b. To treat neutrophil count less than 500 mm to the 3rd power; OR 5. Radiation exposure: a. After radiation therapy in the absence of chemotherapy, if prolonged delays are expected; OR b. After accidental or intentional body irradiation of doses greater than 2 Gy; OR 6. Neuroblastoma: a. In combination with Naxitamab for pediatric individuals one year of age and older and adult individuals with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow demonstrating a partial response, minor response, or stable disease to prior therapy; OR b. In combination with dinutuximab, interleukin-2, and 13-cis-retinoic acid for the treatment of pediatric patients with high-risk neuroblastoma who achieve at least a partial response to prior first line multiagent, multimodal therapy; OR c. In combination with temozolomide, irinotecan, and with dinutuximab or naxitamab-gqgk i. following induction for high-risk disease in the setting of			

		minor response, stable disease, or progressive disease; OR ii. following consolidation in the setting of progressive disease; OR d. In combination with dinutuximab and isotretinoin following consolidation for high-risk disease, if no evidence of disease progression. Tbo-filgrastim 1. Hematopoietic stem cell transplant: a. To promote bone marrow myeloid recovery; OR b. To treat delayed or failed engraftment; OR c. To mobilize stem cells for collection by pheresis; OR 2. Myelodysplastic syndrome: a. Treatment of lower risk disease [(defined as IPSS-R (Very Low, Low, Intermediate), IPSS (Low/Intermediate-1), WPSS (Very Low, Low, Intermediate)] associated with symptomatic anemia, without del(5q), with or without other cytogenetic abnormalities, with serum erythropoietin less than or equal to 500 mU/mL and either of the following: i. Ring sideroblasts greater than or equal to 15% in combination with an erythropoiesis-stimulating agent (ESA); OR ii. Ring sideroblasts less than 15% in combination with lenalidomide and an ESA following no response (despite adequate iron stores) or loss of response to an ESA alone; OR 3. Radiation exposure:			

		a. After accidental or intentional body irradiation of doses greater than 2 Gy. Efbelmalenograstim alfa-vuxw (Ryzneuta), Eflapegrastim-xnst (Rolvedon) 1. Radiation exposure a. After accidental or intentional body irradiation of doses greater than 2 Gy (H-ARS).			