**Policy Review Information**

**CAR T-cell therapy Medical Coverage Guidelines Consolidation**

**Duchenne Muscular Dystrophy Medical Coverage Guidelines Consolidation**

**Oral Oncology Medications Medical Coverage Guidelines Consolidation**

**Medicare Part B Pharmacy Review Updates**

## What's New: 10/15/2025

| New and Revised MCGs: | MCG Number | Update |
|---|---|---|
| 1. Abaloparatide (Tymlos) | 09-J2000-85 | Review and revision to guideline; consisting of updating the references. |
| 2. Acoramidis (Attruby) | 09-J5000-11 | Revision to guideline; updated position statement. |
| 3. Ambulatory Blood Pressure Monitoring (ABPM) | 01-93875-16 | Review: Position statements maintained and references updated. |
| 4. Amivantamab-vmjw (Rybrevant) | 09-J4000-02 | Review and revision to guideline; updated coding and references. |
| 5. Avacincaptad pegol (Izervay) intravitreal injection | 09-J4000-65 | Review and revision to the guideline consisting of revising the position statement to not allow concomitant therapy in the same eye with agents used to treat neovascular/wet AMD (e.g., VEGF inhibitors) and updating references. |
| 6. Bone Morphogenetic Protein (BMP) | 02-20000-32 | Scheduled review. Maintained position statement and updated references. |
| 7. Corticosteroid Intravitreal Implant | 09-J2000-35 | Review and revision to guideline consisting of updating the references. |

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| **8.** | **Cryoablation of Tumors Located in the Kidney, Lung, Breast, Pancreas, or Bone** | 02-99221-12 | Annual review: Position statements maintained and references updated. |
| **9.** | **Daratumumab (Darzalex) Infusion and Daratumumab-Hyaluronidase-fihj (Darzalex Faspro) Injection** | 09-J2000-49 | Revision to guidelines consisting of updating the position statement to change the max frequency of maintenance dosing from every 8 weeks to every 4 weeks and removed maintenance duration limits for the regimens for newly-diagnosed transplant-eligible patients with MM. Updated references. |
| **10.** | **Denosumab (Prolia, Xgeva) Injection** | 09-J1000-25 | Review and revision to guideline; consisting of updating the position statement to include a step through preferred biosimilars. |
| **11.** | **Dinutuximab (Unituxin)** | 09-J2000-42 | Review and revision to guideline; consisting of updating the position statement to include FDA-label or NCCN supported diagnosis. |
| **12.** | **Donanemab-azbt (Kisunla) intravenous infusion** | 09-J4000-94 | Review and revision to guidelines consisting of revising the position statement to include the new dosage titration schedule and to remove the Centiloid measurement of amyloid plaque levels on PET imaging for continuation and updating references. |
| **13.** | **Dostarlimab-gxly (Jemperli)** | 09-J4000-03 | Review and revision to guideline; consisting of updating description, dosing, warnings, and references. |
| **14.** | **Drugs and Biologics without Medical Coverage Guideline** | 09-J0000-68 | Revision to guideline; added Boruzu and Tepylute table 1. |

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| **15.** **Efgartigimod alfa-fcab (Vyvgart, Vyvgart Hytrulo) injection** | 09-J4000-18 | Update to position statement to include Vyvgart Hytrulo prefilled syringe preferred over administration of the Vyvgart and Vyvgart Hytrulo provider administered products. |
| **16.** **Endovascular Stent Grafts for Disorders of the Thoracic Aorta** | 02-33000-29 | Annual review: Position statements maintained; references updated. |
| **17.** **Enzyme Replacement Therapy for Pompe Disease** | 09-J4000-06 | Review and revision to guideline; Updated references. |
| **18.** **Eplontersen (Wainua)** | 09-J4000-77 | Revision to guideline; updated position statement. |
| **19.** **Furosemide (Furoscix) subcutaneous infusion** | 09-J4000-43 | Review and revision to guideline consisting of revising the position statement to include the new FDA-approved indication for the treatment of edema in adult patients with chronic kidney disease, including nephrotic syndrome, removing hepatic cirrhosis and ascites as a contraindication, and updating billing codes and references. |
| **20.** **Gastric Electrical Stimulation** | 01-91000-04 | Revision. Deleted E0765 (refer to MCG 02-61000-04 Transcutaneous Electric Nerve Stimulation (TENS). |
| **21.** **Gene Expression Profile Testing and Circulating Tumor DNA Testing for Predicting Recurrence in Colon Cancer** | 05-86000-29 | Annual review: Position statement maintained; references updated. |
| **22.** **Hereditary Angioedema Drug Therapy** | 09-J1000-08 | Revision to position statement. |

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| **23.** **Ileal Bile Acid Transporter (IBAT) Inhibitors [Maralixibat (Livmarli) Oral Solution and Odevixibat (Bylvay) Capsule]** | 09-J4000-10 | Review and revision to guidelines consisting of updates to the description, position statement, dosage/administration, precautions, billing/coding, related guidelines, and references. The Maralixibat (Livmarli) Oral Solution and Odevixibat (Bylvay) Capsule MCGs are being combined into this single MCG - Ileal Bile Acid Transporter (IBAT) Inhibitors. |
| **24.** **Infrared Energy Therapy and Low Level Laser Therapy** | 09-E0000-44 | Annual review: position statements maintained and references updated. |
| **25.** **Inhaled Nitric Oxide** | 09-J3000-54 | Review and revision to guidelines consisting of updating the references. |
| **26.** **Injectable Bulking Agents for Treatment of Urinary and Fecal Incontinence** | 09-A9000-03 | Scheduled review. Maintained position statement and updated references. |
| **27.** **Interspinous and Interlaminar Stabilization/Distraction (Spacers) and Fixation (Fusion) Devices** | 02-20000-36 | Scheduled review. Revised description. Updated references and maintained position statement. |
| **28.** **Investigational Services** | 09-A0000-03 | Codes 0485T and 0486T (optical coherence tomography of middle ear) reviewed. |
| **29.** **Lysis of Epidural Adhesions** | 02-61000-28 | Scheduled review. Maintained position statement and updated references. |
| **30.** **Magnetic Resonance Angiography (MRA) Abdomen and Pelvis** | 04-70540-21 | Review; no change to position statement. |
| **31.** **Magnetic Resonance Angiography (MRA) Brain (Head)** | 04-70540-18 | Review; no change to position statement. |
| **32.** **Magnetic Resonance Angiography (MRA) Chest** | 04-70540-20 | Review; no change to position statement. |
| **33.** **Magnetic Resonance Angiography (MRA) Extremity (Upper and Lower)** | 04-70540-22 | Review; no change to position statement. |

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| **34.** **Magnetic Resonance Angiography (MRA) Neck** | 04-70540-19 | Review; no change to position statement. |
| **35.** **Magnetic Resonance Angiography (MRA) Spinal Canal** | 04-70540-23 | Review; no change to position statement. |
| **36.** **Mavorixafor (Xolremdi) Capsule** | 09-J4000-91 | Review and revision to guidelines consisting of updating the references. |
| **37.** **Mechanical Stretching Devices for Treatment of Joint Stiffness and Contractures** | 09-E0000-47 | Revision: Occupational therapy added to coverage statements; description updated. |
| **38.** **Minimally Invasive Fusion Techniques** | 02-61000-36 | Scheduled review. Revised description. Maintained position statement and updated references. |
| **39.** **Minimally Invasive Procedures for the Treatment of Gastroesophageal Reflux Disease (GERD) and Dysphagia** | 01-91000-03 | Scheduled review. Revised description. Maintained position statement and updated references. |
| **40.** **Nerve Block Injections** | 02-61000-29 | Revision. Revise criteria for pancreatic cancer; delete criteria subsection titled “all other nerve blocks”; delete (non)coverage statement for imaging performed with nerve blocks for the foot. Revise ICD10 coding and reimbursement information. Update references. |
| **41.** **nipocalimab-aahu (Imaavy)** | 09-J5000-25 | New Medical Coverage Guideline. |
| **42.** **Occlusion of Uterine Arteries Using Transcatheter Embolization** | 02-56000-26 | Review; no change to position statement. Updated references. |
| **43.** **Oscillatory Devices Used in the Home for the Treatment of Cystic Fibrosis and Other Respiratory Disorders** | 09-E0000-28 | Annual review; Position statements maintained; description and references updated. |
| **44.** **Patisiran Sodium (Onpattro)** | 09-J3000-16 | Revision to guideline; updated position statement. |

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| **45.** **Pegcetacoplan (Syfovre) intravitreal injection** | 09-J4000-47 | Review and revision to the guideline consisting of revising the position statement to not allow concomitant therapy in the same eye with agents used to treat neovascular/wet AMD (e.g., VEGF inhibitors) and updating references. |
| **46.** **Prosthetics** | 09-L0000-05 | Scheduled review. Maintained position statement and updated references. |
| **47.** **Ramucirumab (Cyramza) Injection** | 09-J2000-14 | Review and revision to guideline, consisting of updating position statement and references. |
| **48.** **Romosozumab-aqqg (Evenity)** | 09-J3000-33 | Review and revision to guideline consisting of updating the references. |
| **49.** **Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Metastatic Colorectal Cancer (KRAS, NRAS, BRAF, NTRK, RET and HER2)** | 05-86000-28 | Annual review: Position statements, description, title, coding and references updated. |
| **50.** **Speech Generating Devices** | 09-E0000-51 | Scheduled review. Added coverage criteria for replacement SGD and coverage statement E2513 (NeuroNode®). Updated references. |
| **51.** **Tafamidis (Vyndamax, Vyndaqel) Oral** | 09-J3000-41 | Revision to guideline; updated position statement. |
| **52.** **Temporary Prostatic Urethral Stents (Including Implantable Nitinol Devices) and Prostatic Urethral Lift** | 02-54000-21 | Annual review: Position statements maintained, and references updated. |
| **53.** **Teriparatide (Forteo)** | 09-J0000-47 | Review and revision to guideline; consisting of updating the position statement duration of treatment and update to references. |
| **54.** **Transcutaneous Electric Nerve Stimulation (TENS)** | 02-61000-04 | Scheduled review. Maintained position statement and updated references. |

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| **55.** | **Vascular Endothelial Growth Factor Inhibitors for Ocular Neovascularization** | 09-J1000-78 | Review and revision of the guideline consisting of updating the position statement to remove pegaptanib sodium (Macugen) and adding the new FDA approved indications of DME and DR in patients who have previously responded to at least two intravitreal VEGF inhibitor injections for ranibizumab implant (Susvimo) and updating dosing, warnings and precautions (e.g., retinal vasculitis with or without occlusion), billing and references. |
| **56.** | **Vutrisiran (Amvuttra)** | 09-J4000-32 | Revision to guideline; updated position statement. |
| **57.** | **Whole Gland Cryoablation of Prostate Cancer (CSAP)** | 02-54000-14 | Review; no change in position statement. Updated references. |

## What's New: 10/1/2025

| New and Revised MCGs: | MCG Number | Update |
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| **1.** **Abatacept (Orencia) Injection and Infusion** | 09-J0000-67 | Revision: Added ICD-10 code M05.A. Updated ICD-10 code ranges for RA. |
| **2.** **Adalimumab Products (Humira and biosimilars)** | 09-J0000-46 | Revision: Added ICD-10 code M05.A. Updated ICD-10 code ranges for RA. |
| **3.** **Alemtuzumab (Lemtrada) IV** | 09-J2000-27 | Update to ICD10 coding. |
| **4.** **Allogeneic Processed Thymus Tissue_agdc (Rethymic)** | 09-J4000-11 | Revision: Updated HCPCS code Q89.89. |
| **5.** **Anakinra (Kineret) Injection** | 09-J0000-45 | Revision: Added ICD-10 code M05.A. Updated ICD-10 code ranges for RA. |

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| **6.** **Apheresis, Plasmapheresis and Plasma Exchange** | 02-33000-17 | ICD-10 coding update. Deleted G35; added G35A-G35D. |
| **7.** **Asciminib (Scemblix) Tablet** | 09-J4000-22 | Medical Coverage Guideline retired. Scemblix moved to the Oral Oncology Medications MCG. |
| **8.** **Baricitinib (Olumiant) Tablet** | 09-J3000-10 | Revision: Added ICD-10 code M05.A. Updated ICD-10 code ranges for RA. |
| **9.** **Bio-Engineered Skin and Soft Tissue Substitutes, Amniotic Membrane and Amniotic Fluid** | 02-10000-11 | Quarterly CPT/HCPCS coding update. Codes A2036-A2039, Q4383-Q4397 added. |
| **10.** **Brand (Aubagio) Tablet** | 09-J1000-82 | Update to ICD10 coding. |
| **11.** **Brand Gilenya Capsule and Tascenso ODT** | 09-J1000-30 | Update to ICD10 coding. |
| **12.** **Brand Tecfidera, Diroximel fumarate (Vumerity), Monomethyl fumarate (Bafiertam) Capsule** | 09-J1000-96 | Update to ICD10 coding. |
| **13.** **Certolizumab Pegol (Cimzia) Injection** | 09-J0000-77 | Revision: Added ICD-10 code M05.A. Updated ICD-10 code ranges for RA. |
| **14.** **Datopotamab Deruxtecan (Datroway) IV Infusion** | 09-J5000-19 | Revision: Added HCPCS code J9011 and deleted codes C9174 and J9999. |
| **15.** **Dupilumab (Dupixent) Injection** | 09-J2000-80 | Review and revision to guideline consisting of updating the description section, position statement, dosage/administration, precautions, billing/coding, and references. New FDA-approved indications for chronic spontaneous urticaria and bullous pemphigoid. |
| **16.** **Etanercept (Enbrel) Injection** | 09-J0000-38 | Revision: Added ICD-10 code M05.A. Updated ICD-10 code ranges for RA. |

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| **17.** **Evinacumab-dgnb (Evkeeza) Infusion** | 09-J3000-99 | Revision: Added ICD-10 code E78.010 and removed code E78.01. |
| **18.** **Evoked Potentials, Intraoperative Neurophysiologic Monitoring, and Quantitative Electroencephalography (QEEG)** | 01-95805-13 | Annual ICD-10 coding update. Codes G35.A-G35.D added; G35 deleted. |
| **19.** **Fosdenopterin Hydrobromide (Nulibry) IV Infusion** | 09-J3000-95 | Revision: Added HCPCS code J1809 and deleted code J3490. |
| **20.** **Genetic Testing** | 05-82000-28 | Quarterly CPT/HCPCS coding update. Codes 0582U and 0583U added. |
| **21.** **Hereditary Angioedema Drug Therapy** | 09-J1000-08 | Review and revision to position statement, dosing/administration, precautions/warnings, coding, references. |
| **22.** **Hydrocortisone (Khindivi) Oral Solution** | 09-J5000-22 | New Medical Coverage Guideline: Hydrocortisone (Khindivi) oral solution for replacement therapy in pediatric patients 5 to less than 18 years of age with adrenocortical insufficiency who are unable to tolerate or take an alternate dosage forms (e.g., tablets, compounded suspension). |
| **23.** **Immune Globulin Therapy** | 09-J0000-06 | Review and revision to guideline; consisting of updating the position statement to include HyQvia as a non-preferred agent, updating acquired secondary hypogammaglobulinemia, and inclusion of HLH or HLH/MAS with known or suspected Still's disease/sJIA. |
| **24.** **Inclisiran (Leqvio) Injection** | 09-J4000-21 | Revision: Added ICD-10 codes E78.010, E78.011, and E78.019 and removed codes E78.01 and E78.4. Updated the FDA-approved indication wording in the Dosage/Administration section. |

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| **25.** **Infliximab Products [infliximab (Remicade), infliximab-dyyb (Inflectra), infliximab-abda (Renflexis), and infliximab-axxq (Avsola)]** | 09-J0000-39 | Revision: Added ICD-10 code M05.A. Updated ICD-10 code ranges for RA. |
| **26.** **Investigational Services** | 09-A0000-03 | Quarterly CPT/HCPCS Coding Update: Code 0579U added. |
| **27.** **Lenacapavir (Yeztugo) SQ Injection and Tablet** | 09-J5000-23 | New Medical Coverage Guideline: Lenacapavir (Yeztugo) administered every 6 months for all indications including, but not limited to, pre exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 does not meet the definition of medical necessity, as medical necessity is not primarily for convenience (such as extended dosing intervals). |
| **28.** **Lumasiran (Oxlumo) Injection** | 09-J3000-91 | Update to ICD-10 code. |
| **29.** **Multiple Sclerosis Self Injectable Therapy (Interferon beta products and Copaxone)** | 09-J1000-39 | Update to ICD10 coding. |
| **30.** **Myoelectric Prosthetic and Orthotic Components for the Upper Limb** | 09-L0000-07 | Quarterly CPT/HCPCS coding update. Codes L6034-L6039 added; code L6028 revised. |
| **31.** **Natalizumab (Tysabri) IV** | 09-J0000-73 | Update to ICD10 coding. |
| **32.** **Nedosiran Sodium (Rivfloza) SQ Injection** | 09-J4000-79 | Update to ICD-10 coding. |
| **33.** **New-To-Market Program for Medical Benefit Medications** | 09-J4000-30 | Removed Yeztugo SC injection and tablets from the drug list. Added HCPCS code C9305 for Imaavy and code Q5158 for Bomyntra/Conexxence. |
| **34.** **Nilotinib Capsules (Nilceya and Tasigna) and Tablets (Danziten)** | 09-J1000-48 | Revision to guideline consisting of updates to the description section, position statement, dosage/administration, warnings/precautions, and references based on the addition of Nilceya capsules. |
| **35.** **Ocrelizumab (Ocrevus, Ocrevus Zunovo) Infusion** | 09-J2000-78 | Update to ICD10 coding. |

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| **36.** **Ofatumumab (Kesimpta)** | 09-J3000-84 | Update to ICD10 coding. |
| **37.** **Omalizumab (Xolair, Omlyclo)** | 09-J0000-44 | Revision: Added HCPCS code Q5154. |
| **38.** **Oral Oncology Medications** | 09-J3000-65 | Review and revision to guideline; Zegfrovy, Ibtrozi, Avmapki Fakzynja co-pack, Scemblix, and added tablet formulation of Brukinsa (160 mg) to Table 1. |
| **39.** **Ozanimod (Zeposia) Capsules** | 09-J3000-70 | Update to ICD10 coding. |
| **40.** **Palovarotene (Sohonos) Oral Capsules** | 09-J4000-66 | Revision: Updated description of HCPCS code M61.129. |
| **41.** **Pneumatic Compression Devices and Garments** | 09-E0000-31 | Quarterly CPT/HCPCS coding update. Added E0658, E0659. |
| **42.** **Ponesimod (Ponvory) Tablet** | 09-J3000-98 | Update to ICD10 coding. |
| **43.** **Preventive Services** | 01-99385-03 | Revision/update. Revised description. Added HRSA and nationally recognized public and private organizations. Revised reimbursement information. |
| **44.** **Prosthetics** | 09-L0000-05 | Quarterly CPT/HCPCS coding update. Added L5657. |
| **45.** **Pulmonary Hypertension Drug Therapy** | 09-J1000-12 | Review and revision to guideline; consisting of updating references and position statement. |
| **46.** **Remestemcel-l-rknd (Ryoncil) Infusion** | 09-J5000-14 | Revision: Added HCPCS code J3402 and removed code J3590. |
| **47.** **Revakinagene taroretcel-lwey (Encelto) Intravitreal Implant** | 09-J5000-17 | Revision: Added HCPCS code J3403 and removed code J3590. |
| **48.** **Rituximab Products** | 09-J0000-59 | Update to ICD-10 codes. |

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| **49.** | **Sarilumab (Kevzara) Injection** | 09-J2000-88 | Revision: Added ICD-10 code M05.A. Updated ICD-10 code ranges for RA. |
| **50.** | **SARS-CoV-2 Monoclonal Antibodies** | 09-J3000-86 | Revision: Added HCPCS codes M0235, M0236, and Q0235. |
| **51.** | **Siponimod (Mayzent) tablets** | 09-J3000-35 | Update to ICD10 coding. |
| **52.** | **Site of Service Review for Select Surgical Procedures** | 08-00000-01 | New Medical Coverage Guideline. |
| **53.** | **Step Therapy Requirements for Medicare Outpatient (Part B) Medications** | 09-J3000-39 | Review and revision to guidelines, consisting of update to existing ST category: non-preferred drug Ziextenzo [Colony Stimulating Factors]. |
| **54.** | **Subcutaneous Prophylactic Therapy for Hemophilia (Non-Clotting Factor)** | 09-J5000-12 | Revision: Added HCPCS codes J7173 and J7174 and deleted code J3590. |
| **55.** | **Telisotuzumab Vedotin (Emrelis) IV infusion** | 09-J5000-24 | Revision: Added HCPCS code C9306. |
| **56.** | **Teprotumumab (Tepezza) Infusion** | 09-J3000-64 | Revision: Added new ICD-10 codes H05.831, H05.832, H05.833, and H05.839, and removed code E05.00. |
| **57.** | **Tesamorelin (Egrifta) Injection** | 09-J1000-32 | Revision to guideline to update ICD10. |
| **58.** | **Tocilizumab (Actemra) Injection and Infusion, Tocilizumab-aazg (Tyenne) Injection and Infusion, and Tocilizumab-bavi (Tofidence) Infusion** | 09-J1000-21 | Revision: Added ICD-10 code M05.A. |
| **59.** | **Tofacitinib (Xeljanz, Xeljanz XR) Oral Solution, Tablet and Extended-Release Tablet** | 09-J1000-86 | Revision: ICD-10 Codes updated. |
| **60.** | **Transcutaneous Electric Nerve Stimulation (TENS)** | 02-61000-04 | Quarterly CPT/HCPCS coding update. Revised E0765. |
| **61.** | **Ublituximab-xiiy (Briumvi)** | 09-J4000-45 | Update to ICD10 coding. |

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| **62.** **Upadacitinib Tablets (Rinvoq) and Oral Solution (Rinvoq LQ)** | 09-J3000-51 | Revision: Added ICD-10 code M05.A. Updated ICD-10 code ranges for RA. |
| **63.** **Wheelchairs and Wheelchair Accessories** | 09-E0000-35 | Revision. Revised coverage statement for code E1028. Added coverage statement for codes E1032, E1033, E1034. Revised E0986 (quarterly CPT/HCPCS coding update). |

Medical Coverage Guidelines (MCG) for the following oral oncology medications have been consolidated to a single MCG:

09-J3000-65, Oral Oncology Medications

A complete list of previous oral oncology MCGs that have been consolidated is shown below.

| Generic/Brand | MCG Number |
|---|---|
| Abemaciclib (Verzenio) | 09-J2000-93 |
| Acalabrutinib (Calquence) | 09-J2000-94 |
| Afatinib (Gilotrif) | 09-J2000-06 |
| Alectinib (Alecensa) | 09-J2000-56 |
| Alpelisib (Piqray) | 09-J3000-42 |
| Apalutamide (Erleada) | 09-J3000-03 |
| Avapritinib (Ayvakit) | 09-J3000-63 |
| Axitinib (Inlyta) | 09-J1000-67 |
| Binimetinib (Mektovi) | 09-J3000-20 |
| Brigatinib (Alunbrig) | 09-J2000-84 |
| Ceritinib (Zykadia) | 09-J2000-17 |
| Cobimetinib (Cotellic) | 09-J2000-53 |
| Crizotinib (Xalkori) | 09-J1000-57 |
| Dabrafenib (Tafinlar) | 09-J2000-00 |
| Dacomitinib (Vizimpro) | 09-J3000-18 |
| Darolutamide (Nubeqa) | 09-J3000-50 |
| Dasatinib (Sprycel) | 09-J1000-43 |
| Duvelisib (Copiktra) | 09-J3000-14 |
| Enasidenib (Idhifa) | 09-J2000-90 |
| Encorafenib (Braftovi) | 09-J3000-19 |
| Entrectinib (Rozlytrek) | 09-J3000-48 |
| Enzalutamide (Xtandi) | 09-J1000-85 |
| Erdafitinib (Balversa) | 09-J3000-31 |
| Gefitinib (Iressa) | 09-J2000-44 |
| Gilteritinib (Xospata) | 09-J3000-28 |
| Glasdegib (Daurismo) | 09-J3000-27 |
| Idelalisib (Zydelig) | 09-J2000-23 |
| Ivosidenib (Tibsovo) | 09-J3000-13 |
| Lapatinib (Tykerb) | 09-J1000-47 |

| Generic/Brand | MCG Number |
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| Lenvatinib (Lenvima) | 09-J2000-38 |
| Lorlatinib (Lorbrena) | 09-J3000-23 |
| Midostaurin (Rydapt) | 09-J2000-86 |
| Neratinib (Nerlynx) | 09-J2000-83 |
| Niraparib (Zejula) | 09-J2000-77 |
| Olaparib (Lynparza) | 09-J2000-32 |
| Osimertinib (Tagrisso) | 09-J2000-55 |
| Palbociclib (Ibrance) | 09-J2000-34 |
| Panobinostat (Farydak) | 09-J2000-37 |
| Pazopanib (Votrient) | 09-J1000-49 |
| Pexidartinib (Turalio) | 09-J3000-47 |
| Pomalidomide (Pomalyst) | 09-J1000-95 |
| Ponatinib (Iclusig) | 09-J1000-89 |
| Regorafenib (Stivarga) | 09-J1000-83 |
| Rucaparib (Rubraca) | 09-J2000-72 |
| Ruxolitinib (Jakafi) | 09-J1000-63 |
| Selinexor (Xpovio) | 09-J3000-44 |
| Sonidegib (Odomzo) | 09-J2000-45 |
| Sorafenib (Nexavar) | 09-J1000-50 |
| Sunitinib Malate (Sutent) | 09-J1000-51 |
| Talazoparib (Talzenna) | 09-J3000-21 |
| Topotecan HCl (Hycamtin) | 09-J1000-02 |
| Trametinib (Mekinist) | 09-J1000-99 |
| Tretinoin Oral | 09-J1000-61 |
| Trifluridine-Tipiracil (Lonsurf) | 09-J2000-46 |
| Vandetanib (Caprelsa) | 09-J1000-38 |
| Vemurafenib (Zelboraf) | 09-J1000-40 |
| Venetoclax (Venclexta) | 09-J2000-64 |
| Vismodegib (Erivedge) | 09-J1000-66 |

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| Larotrectinib (Vitrakvi) | 09-J3000-25 | Vorinostat (Zolinza) | 09-J1000-54 |
| Lenalidomide (Revlimid) | 09-J0000-80 | Zanubrutinib (Brukinsa) | 09-J3000-62 |

The prior Medical Coverage Guideline (MCG) for this therapy has been consolidated to a single MCG:

09-J3000-93, Exon-Skipping Therapy for Duchenne Muscular Dystrophy

A complete list of previous MCGs that have been consolidated is shown below.

| Generic/Brand | MCG Number |
|---|---|
| Eteplirsen (Exondys 51) | 09-J2000-69 |
| Golodirsen (Vyondys 53) | 09-J3000-55 |
| Viltolarsen (Viltepso) | 09-J3000-78 |

**Medical Coverage Guideline: 09-J2000-91, Tisagenlecleucel (Kymriah) Infusion**

The prior Medical Coverage Guideline (MCG) for this therapy has been consolidated to a single MCG:

09-J3000-94, Chimeric Antigen Receptor (CAR) T-Cell Therapies

A complete list of previous CAR T-cell therapy MCGs that have been consolidated is shown below.

| Generic/Brand | MCG Number |
|---|---|
| Tisagenlecleucel (Kymriah) Infusion | 09-J2000-91 |
| Axicabtagene Ciloleucel (Yescarta) Infusion | 09-J2000-95 |
| Brexucabtagene Autoleucel (Tecartus) Infusion | 09-J3000-71 |
| Lisocabtagene Maraleucel (Breyanzi) | 09-J3000-83 |

## Policy Review Information

Submit new information relevant to a policy when next reviewed by Florida Blue to:

### Florida Blue Medical Policy Area

**4800 Deerwood Campus Parkway**

**Building 900, 5th floor**

**Jacksonville, FL 32246-8273**

# Medicare Part B Pharmacy Review Updates

Effective January 1, 2024, the following updates to the Medical Coverage Guideline Program Exceptions will go into effect:

## Program Exceptions:

**Medicare Advantage Products (Effective 1/1/2024):**

For treatment initiation and continuing therapy under Medicare Advantage:

1. Approve for one (1) year unless a shorter duration is clinically indicated under FDA label (Dosage and Administration section).
2. Approve per duration indicated in the associated Florida Blue Medical Coverage Guideline (MCG) if MCG approval duration exceeds FDA label for clinical evaluation.

In the absence of dosing frequency information within the Local Coverage Determination (LCD) or National Coverage Determination (NCD), refer to the Position Statement section or Dosage and Administration section within the associated Medical Coverage Guideline.