Policy Review Information

Preventive Services 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: 1/1/2025

New and Revised MCGs:	MCG Number	Update
1. Abatacept (Orencia) Injection and I	<u>nfusion</u> 09-J0000-67	Review and revision to guideline consisting of updating the description (NCCN info), position statement, other section, and references. Adalimumab-aaty and Adalimumab-adaz added among the prerequisite therapies for Orencia SC for for RA, PJIA, and PsA. Removed Actemra and added Tyenne among the prerequisite therapies for Orencia SC for PJIA. Update the immune checkpoint inhibitor-related adverse effects indication for Orencia IV. Update to original Table 1 which is now a link out from the Position Statement. Table titles update. Revised wording regarding maximum dosage exceptions. New drugs were added to the list of drugs that are not permitted for use in combination.
2. <u>Abrocitinib (Cibinqo) Tablets</u>	09-J4000-27	Review and revision to guideline consisting of updating the description, position statement, other section, and references. New drugs added to the list of drugs that are not permitted for use in combination.

3. <u>Adalimumab Products (Humira and biosimilars)</u>	09-J0000-46	Review and revision to guideline consisting of updating the position statement, other section, and references. Adalimumab-aaty and Adalimumab-adaz added among the preferred adalimumab products. Update to original Table 1 which is now a link out from the Position Statement. Table titles updated. Revised wording regarding maximum dosage exceptions. New drugs were added to the list of drugs that are not permitted for use in combination. New HCPCS codes.
4. <u>Anakinra (Kineret) Injection</u>	09-J0000-45	Review and revision to guideline consisting of updating the position statement, other section, and references. Kineret for RA moved from a Step 3a agent (double step) to a Step 3c agent (triple step). Adalimumab-aaty and Adalimumab-adaz added among the prerequisite therapies for RA. Update to original Table 1 which is now a link out from the Position Statement. Table titles updated. Revised wording regarding maximum dosage exceptions. New drugs were added to the list of drugs that are not permitted for use in combination.
5. <u>Apremilast (Otezla) Tablet</u>	09-J2000-19	Review and revision to guideline consisting of updating the position statement, other section, and references. Removed specialist requirement for the diagnosis of mild severity plaque psoriasis. For PS indication, divided criteria requirement for adults and pediatrics. Update to original Table 1 which is now a link out from the Position Statement. Table titles updated. New drugs were added to the list of drugs that are not permitted for use in combination.
6. Arimoclomol (Miplyffa) Capsules	09-J5000-04	New Medical Coverage Guideline: Arimoclomol (Miplyffa) capsules for use in

		combination with miglustat for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adult and pediatric patients 2 years of age and older.
7. Baricitinib (Olumiant) Tablet	09-J3000-10	Review and revision to guideline consisting of updating the position statement, other section, and references. Adalimumab-aaty and Adalimumab-adaz added among the prerequisite therapies for RA. Update to original Table 1 which is now a link out from the Position Statement. Table titles updated. Revised wording regarding maximum dosage exceptions. New drugs were added to the list of drugs that are not permitted for use in combination.
8. <u>Bendamustine HCl Injection</u>	09-J2000-40	Revision: Deleted HCPCS codes J9058 and J9059. Revised code J9033. The bendamustine products from Apotex and Baxter are now included under code J9033.
9. <u>Bimekizumab-bkzx (Bimzelx) Injection</u>	09-J4000-70	Review and revision to guideline consisting of updating the position statement, other section, and references. Adalimumab-aaty and Adalimumab-adaz added among the prerequisite therapies for AS, PsA, and PS. Sotyktu added among the prerequisite therapies for PS. New FDA-approved indication for HS. Bimzelx is a step 3c agent for HS. Update to original Table 1 which is now a link out from the Position Statement. Table titles updated. Revised wording regarding maximum dosage exceptions. New drugs were added to the list of drugs that are not permitted for use in combination.

10. Bio-Engineered Skin and Soft Tissue Substitutes, Amniotic Membrane and Amniotic Fluid	02-10000-11	Annual CPT/HCPCS coding update. Codes 15011-15018, C8002,Q4346-Q4353 added.
11. Brodalumab (Siliq) Injection	09-J2000-79	Review and revision to guideline consisting of updating the position statement, precautions, other section, and references. Adalimumab-aaty, Adalimumab-adaz, and Sotyktu added among the prerequisite therapies for PS. Update to original Table 1 which is now a link out from the Position Statement. Table titles updated. Revised wording regarding maximum dosage exceptions. New drugs were added to the list of drugs that are not permitted for use in combination.
12. <u>Buprenorphine (Brixadi, Sublocade)</u> <u>Subcutaneous Injection</u>	09-J2000-68	Revision: Added HCPCS code G0533 and deleted code J0570. Probuphine was deleted from the MCG. Probuphine was removed from the market in October 2020 and is now an obsolete product.
13. Cardiac Monitoring Devices	01-93000-05	Annual CPT/HCPCS coding update. Code G0555 added.
14. <u>Certolizumab Pegol (Cimzia) Injection</u>	09-J0000-77	Review and revision to guideline consisting of updating the position statement, other section, and references. Adalimumab-aaty and Adalimumab-adaz added among the prerequisite therapies for AS, CD, PJIA, PsA, PS, and RA. Entyvio (vedolizumab) subcutaneous injection (now a step 1a agent) added among the prerequisite therapies for CD. Sotyktu (deucravacitinib) (now a step 1a agent) added among the prerequisite therapies for PS. Update to original Table 1 which is now a link out from the Position Statement. Table titles updated. Revised wording regarding maximum dosage exceptions. New drugs were added to the

		list of drugs that are not permitted for use in combination.
15. <u>Chimeric Antigen Receptor (CAR) T-Cell</u> <u>Therapies</u>	09-J3000-94	Review and revision to guideline consisting of updating the description section (NCCN info), position statement, dosage/administration, precautions, billing/coding, and references. Addition of obecabtagene autoleucel (Aucatzyl approved in November 2024 for "for "the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)". Added boxed warning of "T cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19- directed genetically modified autologous T cell immunotherapies" to all CAR T-cell therapies as this is now a class- wide warning in the labeling.
16. Crovalimab (Piasky)	09-J4000-95	Revision: Added HCPCS code 1307 and deleted code J3590.
17. <u>Deucravacitinib (Sotyktu) Tablet</u>	09-J4000-37	Review and revision to guideline consisting of updating the position statement, other section, and references. Sotyktu moved to a Step 1a agent. Update to original Table 1 which is now a link out from the Position Statement. Table titles updated. New drugs were added to the list of drugs that are not permitted for use in combination.
18. Diabetic Self-Management Training and Educational Supplies	01-99000-02	Annual CPT/HCPCS coding update. Revised 98960, 98961, 98962.
19. Dupilumab (Dupixent) Injection	09-J2000-80	Review and revision to guideline consisting of updating the position statement, other section, and references. New FDA-approved indication for COPD. New drugs were added to the list of drugs

		that are not permitted for use in combination.
20. <u>Elafibranor (Iqirvo) Tablet</u>	09-J4000-93	Review and revision to the guideline consisting of updating the position statement to not allow for concomitant use with seladelpar (Livdelzi).
21. <u>Esketamine (Spravato) Nasal Spray</u>	09-J3000-37	Revision to guideline consisting of updating the position statement to clarify dosing associated with MDD with acute suicidal ideation or behavior and treatment-resistant depression.
22. <u>Etanercept (Enbrel) Injection</u>	09-J0000-38	Review and revision to guideline consisting of updating the description, position statement, other section, and references. Update to original Table 1 which is now a link out from the Position Statement. Table titles updated. Revised wording regarding maximum dosage exceptions. New drugs added to the list of drugs that are not permitted for use in combination.
23. <u>Etrasimod (Velsipity) Tablet</u>	09-J4000-72	Review and revision to guideline consisting of updating the position statement, other section, and references. Adalimumab-aaty, Adalimumab-adaz, Entyvio SC, and Tremfya added among the prerequisite therapies for UC. Update to original Table 1 which is now a link out from the Position Statement. Table titles updated. Revised wording regarding maximum dosage exceptions. New drugs were added to the list of drugs that are not permitted for use in combination.
24. Exagamglogene autotemcel (Casgevy) suspension for IV infusion	09-J4000-82	Revision: Added HCPCS code J3392 and deleted code J3590.

25. External Insulin Infusion Pumps and Continuous Glucose Monitors	01-99000-03	Annual CPT/HCPCS coding update. Added G0564, G0565.
26. Fidanacogene Elaparvovec (Beqvez)	09-J4000-92	Revision: Added HCPCS code J1414 and deleted codes C9172 and J3590.
27. <u>Genetic Testing</u>	05-82000-28	Annual CPT/HCPCS coding update. Code 96041 added; code 96040 deleted.
28. <u>Genetic Testing for Hereditary Breast</u> <u>Ovarian Cancer Syndrome and Other High-</u> <u>Risk Cancers (BRCA1, BRCA2, PALB2)</u>	05-82000-30	Annual CPT/HCPCS coding update. Code 96041 added; code 96040 deleted.
29. <u>Genetic Testing for Lynch Syndrome and</u> <u>Other Inherited Colon Cancer Syndromes</u>	05-82000-31	Annual CPT/HCPCS coding update. Code 96041 added.
30. <u>Golimumab (Simponi, Simponi Aria)</u> Injection and Infusion	09-J1000-11	Review and revision to guideline consisting of updating the position statement, other section, and references. Adalimumab-aaty and Adalimumab-adaz added among the prerequisite therapies for AS, PsA, RA, and UC for Simponi. Entyvio SC and Tremfya added among the prerequisite therapies for UC for Simponi (when other drugs are contraindication or not clinically appropriate). Update to original Table 1 which is now a link out from the Position Statement. Table titles updated. Revised wording regarding maximum dosage exceptions for Simponi. New drugs were added to the list of drugs that are not permitted for use in combination.
31. Granulocyte Colony Stimulating Factors	09-J0000-62	Revision: Added HCPCS code C9173.
32. <u>Guselkumab (Tremfya) Injection</u>	09-J2000-87	Review and revision to guideline consisting of updating the position statement, other section, and references. Update to original Table 1 which is now a link out from the Position Statement. Table titles updated. Revised wording regarding maximum dosage exceptions for

33. Immune Globulin Therapy 09-J0000-06 Revision: Added HCPCS code J1552.
33. Immune Globulin Therapy09-J0000-06Revision: Added HCPCS code J1552.
34. Implantable Cardioverter 02-33000-34 Annual CPT/HCPCS coding update. Codes 0915T-0931T added.
35. In Vitro Chemoresistance and Chemosensitivity Assays 05-86000-11 Annual CPT/HCPCS coding update. Code 0564T deleted.
 36. Infliximab Products [infliximab (Remicade), infliximab-dyyb (Inflectra), infliximab-abda (Renflexis), and infliximab-axxq (Avsola)] 09-J0000-39 Review and revision to guideline consisting of updating the position statement, other section, and references. Zymfentra moved from a step 3c agent (triple step) to a step 3a agent (double step) for CD and UC. Adalimumab-aaty, Adalimumab-adaz, and Entyvio SC added among the prerequisite therapies for Zymfentra for CD and UC. Tremfya added among the prerequisite therapies for Zymfentra for UC. Revised wording regarding maximum dosage exceptions for Zymfentra. Update to original Table 1 which is now a link out from the Position Statement. Table titles updated. New drugs were added to the list of drugs that are not permitted for use in combination.
37. Investigational Services 09-A0000-03 Annual CPT/HCPCS Coding Update: Codes 0933T, 0934T, 0935T, C1735, C1736, G0552, G0553, G0554 added. Codes G016T-0618T, 0456U deleted.
38. <u>Ixekizumab (Taltz) Injection</u> 09-J2000-62 Review and revision to guideline consisting of updating the position statement, dosage/administration, precautions, other section, and references. Adalimumab-aaty and Adalimumab-adaz added among the prerequisite therapies for AS, PsA, and PS

		Sotyktu added among the prerequisite therapies for PS. Update to original Table 1 which is now a link out from the Position Statement. Table titles updated. Weight- based dosing for pediatric PS added to the Position Statement. Revised wording regarding maximum dosage exceptions. New drugs were added to the list of drugs that are not permitted for use in combination.
39. <u>Knee Arthroscopy and Open, Non-</u> <u>Arthroplasty Knee Repair</u>	02-20000-65	Annual CPT/HCPCS coding update. Added C8003.
40. Lebrikizumab-lbkz (Ebglyss) Injection	09-J5000-00	New Medical Coverage Guideline.
41. Levacetylleucin (Aqneursa) Oral Suspension	09-J5000-05	New Medical Coverage Guideline: Levacetylleucin (Aqneursa) oral suspension for the treatment of neurological manifestations of Niemann- Pick disease type C (NPC) in adults and pediatric patients weighing ≥15 kg.
42. <u>Magnetic Resonance - Guided High Intensity</u> <u>Focused Ultrasound Ablation</u>	02-56000-27	Annual CPT/HCPCS coding update. Added 61715. Deleted 0398T.
43. <u>Mechanical Stretching Devices for</u> <u>Treatment of Joint Stiffness and</u> <u>Contractures</u>	09-E0000-47	Annual CPT/HCPCS Coding Update: Codes E1803, E1804, E1807, E1808, E1813, E1814, E1822, E1823, E1826-E1829 added; codes E1800, E1805, E1810, E1815, E1825, E1830 revised.
44. <u>Mirikizumab-mrkz (Omvoh®) Injection and</u> Infusion	09-J4000-71	Review and revision to guideline consisting of updating the position statement, other section, and references. Omvoh moved from a Step 3b agent (double step) to a Step 2 agent (single step). Adalimumab-aaty, Adalimumab- adaz, and Entyvio SC added among the prerequisite therapies for UC. Update to original Table 1 which is now a link out from the Position Statement. Table titles

		updated. Revised wording regarding maximum dosage exceptions. New drugs were added to the list of drugs that are not permitted for use in combination.
45. Nab-Paclitaxel Injection (Abraxane)	09-J1000-05	Revision: Removed HCPCS code J9259.
46. Nemolizumab-ilto (Nemluvio) Injection	09-J4000-99	New Medical Coverage Guideline.
47. <u>Neurolysis, Ablation</u>	02-61000-34	Annual CPT/HCPCS coding update. Added C9809.
48. Neuropsychological Testing	01-95805-14	Scheduled review. Revised description and position statement. Updated references.
49. <u>New-To-Market Program for Medical Benefit</u> <u>Medications</u>	09-J4000-30	Additions of Wezlana (ustekinumab-auub) SC injection and IV infusion to the drug list.
50. <u>Obeticholic Acid (Ocaliva) Tablet</u>	09-J2000-65	Review and revision to the guideline consisting of updating the position statement to not allow for concomitant use with seladelpar (Livdelzi).
51. Oral Therapy for Gaucher and Pompe Disease	09-J0000-76	Revision to guideline; consisting of updating position statement, dosage/administration
52. Palopegteriparatide (Yorvipath) SQ injection	09-J5000-03	New Medical Coverage Guideline: Palopegteriparatide (Yorvipath) SQ injection for the treatment of hypoparathyroidism in adults who have tried and had an inadequate response to maximally tolerated calcium AND vitamin D supplements.
53. Pemetrexed (Alimta, Pemfexy) IV	09-J1000-01	Revision: Added HCPCS code J9292.
54. <u>Percutaneous Electrical Nerve Stimulation</u> (PENS)	02-61000-03	Annual CPT/HCPCS coding update. Added C9807.

55. Physical Therapy (PT) and Occupational Therapy (OT)	01-97000-01	Annual CPT/HCPCS coding update. Deleted 96003.
56. <u>Preventive Services</u>	01-99385-03	Annual CPT/HCPCS coding update. Added 87626. Deleted 90630, 90654, 96040, 99441-99443, 0500T, G0106, G0120, and G0122.
57. Reconstructive Surgery/ Cosmetic Surgery	02-12000-01	Annual CPT/HCPCS coding update. Deleted 15819.
58. <u>Risankizumab-rzaa (Skyrizi) Injectionand</u> Infusion	09-J3000-45	Review and revision to guideline consisting of updating the position statement, other section, and references. Update to original Table 1 which is now a link out from the Position Statement. Table titles updated. Revised wording regarding maximum dosage exceptions. Clarified that the age requirement that exists for subcutaneous Skyrizi also applies to intravenous Skyrizi. New drugs added to the list of drugs that are not permitted for use in combination.
59. <u>Ritlecitinib (Litfulo) Capsule</u>	09-J4000-57	Review and revision to guideline consisting of updating the position statement, other section, and references. Revised wording regarding dosage limit exceptions. New drugs added to the list of drugs that are not permitted for use in combination.
60. Romiplostim Injection (Nplate)	09-J0000-88	Revision: Added HCPCS code J2802 and deleted code J2796.
61. <u>Sarilumab (Kevzara) Injection</u>	09-J2000-88	Review and revision to guideline consisting of updating the description (NCCN info), position statement, other section, and references. Adalimumab-aaty and Adalimumab-adaz added among the prerequisite therapies for PJIA and RA. Update to original Table 1 which is now a

		link out from the Position Statement. Table titles updated. Revised wording regarding maximum dosage exceptions. New drugs were added to the list of drugs that are not permitted for use in combination.
62. <u>Scanning Computerized Ophthalmic</u> <u>Diagnostic Imaging</u>	01-92000-17	Annual CPT/HCPCS coding update. Added 92137; revised 92132, 92133, 92134.
63. <u>Secukinumab (Cosentyx) Injection and</u> Infusion	09-J2000-30	Review and revision to guideline consisting of updating the description, position statement, other section, and references. Update to original Table 1 which is now a link out from the Position Statement. Table titles updated. Revised wording regarding maximum dosage exceptions. Clarified that the age requirement that exists for subcutaneous Cosentyx also applies to intravenous Cosentyx. New drugs added to the list of drugs that are not permitted for use in combination.
64. <u>Seladelpar (Livdelzi) Capsule</u>	09-J5000-02	New Medical Coverage Guideline: Seladelpar (Livdelzi) for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA.
65. Site of Care Guideline for Select Specialty Medications	09-J3000-46	Revision: HCPCS code update for Tyenne,
66. Spesolimab-sbzo (Spevigo) Subcutaneous Injection and Intravenous Infusion	09-J4000-36	Review and revision to guideline consisting of updating the other section and references. New drugs added to the list of drugs that are not permitted for use in combination.
67. <u>Step Therapy Requirements for Medicare</u> <u>Outpatient (Part B) Medications</u>	09-J3000-39	Review and revision to position statement and guidelines, addition of non-preferred

		drugs for ST programs: Hercessi, Herzuma, Ogivri [Oncology], Nypozi [Colony Stimulating Factors], Yimmugo [Immune Globulins], Pavblu [Ophthalmic Agents], PiaSky [Complement Inhibitors], remove shortage statement [Erythropoeisis Stimulating Agents], and addition of new ST programs: Asthma Therapy [Cinqair], Immune Globulin Antibody Agents [Vyvgart Hytrulo]; and additional programs to ST categories: Autoimmune Therapy [Actemra, Tofidence, Renflexis, Zymfentra].
68. <u>Temporary Prostatic Urethral Stents</u> (Including Implantable Nitinol Devices) and Prostatic Urethral Lift	02-54000-21	Annual CPT/HCPCS Coding Update: Codes 53865, 53866 added; code C9769 deleted.
69. <u>Tildrakizumab-asmn (Ilumya)</u>	09-J3000-04	Review and revision to guideline consisting of updating the position statement, other section, and references. New drugs added to the list of drugs that are not permitted for use in combination.
70. <u>Tocilizumab (Actemra) Injection and Infusion, Tocilizumab-aazg (Tyenne)</u> Injection and Infusion, and Tocilizumab-bavi (Tofidence) Infusion	09-J1000-21	Review and revision to guideline consisting of updating the position statement, other section, and references. Adalimumab-aaty and Adalimumab-adaz added among the preferred adalimumab products. Subcutaneous (SC) tocilizumab- aazg (Tyenne) is now the preferred SC tocilizumab product. Tyenne SC added as a step 1a agent for GCA, SJIA, and SSc-ILD, and added as a step 2 agent (stepped through a preferred adalimumab product) for PJIA and RA. Subcutaneous (SC) tocilizumab (Actemra) was moved to step 2 (stepped though Tyenne) for GCA, SJIA, and SSc-ILD, and moved from a step 2 to step 3b for PJIA and RA (stepped though both Tyenne and preferred adalimumab product). Intravenous (IV) tocilizumab- aazg (Tyenne) is now the preferred IV tocilizumab product. Both IV tocilizumab

		(Actemra) and IV tocilizumab-bavi (Tofidence) are non-preferred and stepped though Tyenne IV for both new starts and continuation of therapy. Update to original Table 1 which is now a link out from the Position Statement. Table titles updated. Revised wording regarding maximum dosage exceptions for Actemra SC and Tyenne SC. New drugs were added to the list of drugs that are not permitted for use in combination.
71. <u>Tofacitinib (Xeljanz, Xeljanz XR) Oral</u> <u>Solution, Tablet and Extended-Release</u> <u>Tablet</u>	09-J1000-86	Review and revision to guideline consisting of updating the position statement, other section, and references. Adalimumab-aaty and Adalimumab-adaz added among the preferred adalimumab products. Update to original Table 1 which is now a link out from the Position Statement. Table titles updated. Revised wording regarding maximum dosage exceptions. New drugs were added to the list of drugs that are not permitted for use in combination.
72. <u>Tralokinumab-ldrm (Adbry) Injection</u>	09-J4000-20	Review and revision to guideline consisting of updating the position statement, other section, and references. New drugs were added to the list of drugs that are not permitted for use in combination.
73. Transcranial Doppler Studies	01-93875-17	Annual CPT/HCPCS coding update. Revised 93893. Deleted 93890.
74. Trastuzumab (Herceptin) Injection	09-J0000-86	Revision to guideline; Updated position statement and HCPCS coding.
75. Tumor/Genetic Markers	05-86000-22	Annual CPT/HCPCS coding update. Codes 82233, 82234, 84393, 84394 added.

76. <u>Upadacitinib Tablets (Rinvoq) and Oral</u> <u>Solution (Rinvoq LQ)</u>	09-J3000-51	Review and revision to guideline consisting of updating the description, position statement, other section, and references. Adalimumab-aaty and Adalimumab-adaz added among the preferred adalimumab products. Revised wording regarding maximum dosage exceptions. Update to original Table 1 which is now a link out from the Position Statement. Table titles updated. New drugs were added to the list of drugs that are not permitted for use in combination.
77. <u>Ustekinumab (Stelara) Injection and Infusion</u>	09-J1000-16	Review and revision to guideline consisting of updating the description, position statement, other section, and references. Added pediatric-specific dosing for PS and PsA (when under 60 kg) to the Position Statement. Update to original Table 1 which is now a link out from the Position Statement. Table titles updated. Revised wording regarding maximum dosage exceptions. New drugs added to the list of drugs that are not permitted for use in combination. New HCPCS codes.
78. <u>Vadadustat (Vafseo)</u>	09-J4000-90	Revision: Added HCPCS code J0901 and deleted code J3490.
79. Vagus Nerve Stimulation	02-61000-22	Annual CPT/HCPCS coding update. Added 0908T, 0909T, 0910T, 0911T, 0912T.
80. <u>Vedolizumab (Entyvio) Injection and</u> Infusion	09-J2000-18	Review and revision to guideline consisting of updating the description, position statement, billing/coding, other section, and references. Entyvio SC moved from step 3b agent (double step) to step 1a (no biologic agent step) for CD and UC. Refractory acute GVHD added as an indication for Entyvio IV. Update to original Table 1 which is now a link out from the Position Statement. Table titles

updated. Revised wording regarding maximum dosage exceptions for Entyvio SC. New drugs were added to the list of drugs that are not permitted for use in combination. 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	Generic/Brand	MCG Number
Abemaciclib (Verzenio)	09-J2000-93	Lenvatinib (Lenvima)	09-J2000-38
Acalabrutinib (Calquence)	09-J2000-94	Lorlatinib (Lorbrena)	09-J3000-23
Afatinib (Gilotrif)	09-J2000-06	Midostaurin (Rydapt)	09-J2000-86
Alectinib (Alecensa)	09-J2000-56	Neratinib (Nerlynx)	09-J2000-83
Alpelisib (Piqray)	09-J3000-42	Niraparib (Zejula)	09-J2000-77
Apalutamide (Erleada)	09-J3000-03	Olaparib (Lynparza)	09-J2000-32
Avapritinib (Ayvakit)	09-J3000-63	Osimertinib (Tagrisso)	09-J2000-55
Axitinib (Inlyta)	09-J1000-67	Palbociclib (Ibrance)	09-J2000-34
Binimetinib (Mektovi)	09-J3000-20	Panobinostat (Farydak)	09-J2000-37
Brigatinib (Alunbrig)	09-J2000-84	Pazopanib (Votrient)	09-J1000-49
Ceritinib (Zykadia)	09-J2000-17	Pexidartinib (Turalio)	09-J3000-47
Cobimetinib (Cotellic)	09-J2000-53	Pomalidomide (Pomalyst)	09-J1000-95
Crizotinib (Xalkori)	09-J1000-57	Ponatinib (Iclusig)	09-J1000-89
Dabrafenib (Tafinlar)	09-J2000-00	Regorafenib (Stivarga)	09-J1000-83
Dacomitinib (Vizimpro)	09-J3000-18	Rucaparib (Rubraca)	09-J2000-72
Darolutamide (Nubeqa)	09-J3000-50	Ruxolitinib (Jakafi)	09-J1000-63
Dasatinib (Sprycel)	09-J1000-43	Selinexor (Xpovio)	09-J3000-44
Duvelisib (Copiktra)	09-J3000-14	Sonidegib (Odomzo)	09-J2000-45
Enasidenib (Idhifa)	09-J2000-90	Sorafenib (Nexavar)	09-J1000-50
Encorafenib (Braftovi)	09-J3000-19	Sunitinib Malate (Sutent)	09-J1000-51
Entrectinib (Rozlytrek)	09-J3000-48	Talazoparib (Talzenna)	09-J3000-21
Enzalutamide (Xtandi)	09-J1000-85	Topotecan HCI (Hycamtin)	09-J1000-02
Erdafitinib (Balversa)	09-J3000-31	Trametinib (Mekinist)	09-J1000-99
Gefitinib (Iressa)	09-J2000-44	Tretinoin Oral	09-J1000-61
Gilteritinib (Xospata)	09-J3000-28	Trifluridine-Tipiracil (Lonsurf)	09-J2000-46
Glasdegib (Daurismo)	09-J3000-27	Vandetanib (Caprelsa)	09-J1000-38
Idelalisib (Zydelig)	09-J2000-23	Vemurafenib (Zelboraf)	09-J1000-40
lvosidenib (Tibsovo)	09-J3000-13	Venetoclax (Venclexta)	09-J2000-64
Lapatinib (Tykerb)	09-J1000-47	Vismodegib (Erivedge)	09-J1000-66

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

Preventive Services Information

Preventive services include a broad range of services (including screening tests, counseling, and immunizations/vaccines). Florida Blue has adopted the U.S. Preventive Services Task Force (USPSTF) Guide to Clinical Preventive Services: [childhood and adolescent immunization schedule approved by: the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP); adult immunization schedule approved by: the Advisory Committee on Immunization Practices (ACIP), the American College of Obstetricians and Gynecologists (ACOG), and the American Academy of Family Physicians (AAFP)].

Centers for Disease Control and Prevention (CDC) (recommended vaccines and immunizations).

<u>Guide to Clinical Preventive Services</u> (recommendations made by the USPSTF for clinical preventive services).

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.