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What's New: 4/1/2025

New and Revised MCGs:	MCG Number	Update
1. Acoramidis (Attruby)	09-J5000-11	New Medical Coverage Guideline.
2. Aducanumab-avwa (Aduhelm)	09-J4000-01	Policy archived and retired.
3. Afamitresgene Autoleucel (Tecelra)	09-J4000-96	Revision: Added HCPCS code Q2057 and deleted code J9999.
4. Axatilimab (Niktimvo)	09-J4000-98	Revision: Added HCPCS code J9038 and deleted code J9999.
5. Bio-Engineered Skin and Soft Tissue Substitutes, Amniotic Membrane and Amniotic Fluid	02-10000-11	Quarterly CPT/HCPCS coding update. Codes A2030-A2035, Q4354-Q4367; code Q4231 deleted.
6. Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.doc	09-J9000-02	Revision: Additions of Ustekinumab and Stegeyma.
7. Certolizumab Pegol (Cimzia) Injection	09-J0000-77	Revision to guidelines consisting of updates to the position statement. Self-administered Cimzia moved from a step 3c (triple step) to step 3a (double step) agent for PJI. For the Crohn's disease indication, self-administered Cimzia is a 3a agent (double step), but the step no

longer always requires an adalimumab product.

8. Chimeric Antigen Receptor (CAR) T-Cell Therapies	09-J3000-94	Revision: Added HCPCS code C9301.
9. Clotting Factors and Coagulant Blood Products	09-J0000-34	Revision: Removed Hemlibra from Medical Coverage Guideline.
10. Crinecerfont (Crenessity) Capsule and Oral Solution	09-J5000-08	New Medical Coverage Guideline: Crinecerfont (Crenessity) as adjunctive treatment to glucocorticoid replacement to control androgens in adults and pediatric patients 4 years of age and older with classic congenital adrenal hyperplasia.
11. Denileukin diftitox-cxdl (Lymphir) injection	09-J4000-97	Revision: Added HCPCS code J9161 and deleted code J9999.
12. Deutivacaftor-Tezacaftor-Vanzacaftor (Alyftrek)	09-J5000-10	New Medical Coverage Guideline.
13. Eculizumab (Soliris) Injection	09-J1000-17	Revision: Added HCPCS code J1299 and deleted code J1300. New code for Soliris with different billing units.
14. External Insulin Infusion Pumps and Continuous Glucose Monitors	01-99000-03	Quarterly CPT/HCPCS coding update. Deleted G0564, G0565.
15. Foscarbidopa-Foslevodopa (Vyalev) subcutaneous infusion	09-J5000-09	New Medical Coverage Guideline: Foscarbidopa-foslevodopa (Vyalev) subcutaneous infusion for the treatment of motor fluctuations in adults with advanced Parkinson's disease.
16. Granulocyte Colony Stimulating Factors	09-J0000-62	Revision: Added HCPCS code C9173.
17. Hormone Replacement	09-J1000-24	Revision to guidelines; consisting of updating the position statement and coding to include Azmiro (J1072).

18. <u>Laboratory Tests Post Transplant and for Heart Failure</u>	05-86000-24	Quarterly CPT/HCPCS coding update. Code 0540U added.
19. <u>Mechanical Stretching Devices for Treatment of Joint Stiffness and Contractures</u>	09-E0000-47	Quarterly CPT/HCPCS coding update. Code E1832 added; codes E1801, E1811, E1816, E1818, E1841 revised.
20. <u>Mirikizumab-mrkz (Omvoh®) Injection and Infusion</u>	09-J4000-71	Revision to guideline consisting of updating the description section, position statement, dosage/administration section, billing/coding information, and references based on a new FDA approved indication for CD. Omvoh is a Step 2 agent (single step) for CD.
21. <u>Myoelectric Prosthetic and Orthotic Components for the Upper Limb</u>	09-L0000-07	Quarterly CPT/HCPCS coding update. Code L6700 added.
22. <u>New-To-Market Program for Medical Benefit Medications</u>	09-J4000-30	Revision: Added Bkemv (eculizumab-aeeb) IV infusion and Epysqli (eculizumab-aagh) IV infusion to the drug list. Removed Vyalev (foscarbidopa/foslevodopa) injection from the drug list. Added HCPCS code Q9999 for Otulfi and code Q5147 for Pavblu.
23. <u>Ocrelizumab (Ocrevus, Ocrevus Zunovo) Infusion</u>	09-J2000-78	Revision: Added HCPCS code J2351.
24. <u>Olezarsen Sodium (Tryngolza) SQ Injection</u>	09-J5000-07	New Medical Coverage Guideline: Olezaren (Tryngolza) as an adjunct to diet for the reduction of triglycerides in adults with familial chylomicronemia syndrome (FCS).
25. <u>Oral Oncology Medications</u>	09-J3000-65	Review and revision to guideline; addition of Revuforj tablets, Itovebi tablets, and Ensacove capsules to Table 1.
26. <u>Pneumatic Compression Devices and Garments</u>	09-E0000-31	Quarterly CPT/HCPCS coding update. Added A6515, A6516, A6517, A6518, A6519, A6611.

27. Preferred Agents Table and Drug List	09-J9000-01	Revision. Omvoh added as a Step 2 agent for CD. Cimzia moved from a Step 3c agent to a Step 3a agent for PJIA. Cimzia for CD no longer always requires an adalimumab product as a required Step 1 agent.
28. Prosthetics	09-L0000-05	Quarterly CPT/HCPCS coding update. Deleted L8010.
29. SARS-CoV-2 Monoclonal Antibodies	09-J3000-86	Revision: Deleted HCPCS codes retired by CMS for products no longer EUA approved [includes all products except pemivibart (Pemgarda)].
30. Subcutaneous Prophylactic Therapy for Hemophilia (Non-Clotting Factor)	09-J5000-12	New Medical Coverage Guideline.
31. Tenapanor (Xphozah)	09-J5000-13	New Medical Coverage Guideline.
32. Ustekinumab (Stelara) Injection and Infusion	09-J1000-16	Revision: Added HCPCS code Q9999.

What's New: 3/15/2025

New and Revised MCGs:	MCG Number	Update
33. ADAMTS13, recombinant-krhn (Adzynma) IV Infusion	09-J4000-75	Review and revision to guidelines consisting of updating the references.
34. Aprepitant (Cinvanti) and fosaprepitant (Focinvez) injectable therapy	09-J2000-60	Review and revision to guideline; consisting of including Focinvez, and updating dosing, precautions, coding, and references.
35. Bevacizumab (Avastin), bevacizumab-awwb (Mvasi), bevacizumab-bvzr (Zirabev), and bevacizumab-maly (Alymsys), bevacizumab-tnjn (Avzivi), and bevacizumab-adcd (Vegzelma) Injection	09-J0000-66	Review and revision to guideline; consisting of updating the position statement to include hereditary hemorrhagic telangiectasia and vaginal cancer. Revisions included for ampullary, cervical, CNS, colon, hepatic, kidney,

ovarian, soft tissue sarcoma, uterine cancer. Updates to coding and references.

36. Ciplacizumab-yhdp (Cablivi)	09-J3000-32	Review and revision to guideline; consisting of updating references.
37. Chelation Therapy	01-99000-07	Scheduled review. Revised description, maintained position statement and updated references.
38. Computed Tomography Angiography (CTA) Abdomen and Pelvis	04-70450-04	Review; no change in position statement.
39. Diagnosis and Treatment of Temporomandibular Joint Disorder	02-20000-12	Scheduled review. Revised description, maintained position statement and updated references.
40. Donanemab-azbt (Kisunla) intravenous infusion	09-J4000-94	Review and revision to the guideline consisting of revising the Position Statement to extend the range for the MMSE assessment from 22-30 to 20-30 for “mild cognitive impairment” and the baseline assessment for amyloid beta plaque from 6 months to 1 year.
41. Drugs and Biologics without Medical Coverage Guideline	09-J0000-68	Revision to guideline; added Bizengri, RegeneCyte, Unloxcyt, Vyloy, and Ziihera to table 1
42. Elafibranor (Iqirvo) Tablet	09-J4000-93	Review and revision to the guideline consisting of updating the position statement to remove documentation requirements and allow prescribing in consultation with a gastroenterologist or hepatologist.
43. Endothelial Keratoplasty and Corneal Collagen Cross-Linking	02-65000-15	Scheduled review. Revised description, maintained position statement, and updated references.

44. Frenectomy or Frenotomy for Ankyloglossia (Tongue-Tie) in Newborns, Children, & Adolescents	02-40000-25	Review: Position statements maintained; references updated.
45. Functional Magnetic Resonance Imaging (fMRI)	04-70540-10	Review; no change in position statement. Updated references.
46. Gastric Electrical Stimulation	01-91000-04	Scheduled review. Maintained position statement and updated references.
47. Gender Affirmation Surgery	02-55900-01	Review: Position statements maintained and references updated.
48. Glofitamab-gxbm (Columvi) IV Infusion	09-J4000-60	Revision to guideline consisting of updating the position statement to add new 1 and 2A NCCN recommendations for second-line or subsequent therapy and use in combination with gemcitabine and oxaliplatin.
49. Imatinib (Imkeldi) Oral Solution	09-J5000-15	New Medical Coverage Guideline.
50. Interstitial Laser Therapy	02-99221-16	Review; no change in position statement. Updated references.
51. Intracellular Micronutrient Analysis	05-86000-31	Review: Position statements maintained and references updated.
52. Lecanemab-irmb (Leqembi) intravenous infusion	09-J4000-41	Review and revision to the guideline consisting of revising the Position Statement to extend the range for the MMSE assessment from 22-30 to 20-30 for “mild cognitive impairment” and the baseline assessment for amyloid beta plaque from 6 months to 1 year, updating the new FDA approved extended interval dosing to every 4 weeks after 18 months of the initiation phase, revising precaution and box warning language, and updating references.

53. Medical & Surgical Management of Sleep Apnea, Snoring, and Other Conditions of the Soft Palate and Nasal Passages	02-40000-16	Code 64568 added.
54. Nerve Block Injections	02-61000-29	Scheduled review. Revised description and ICD10 coding table. Revised position statement to include coverage statement for nerve blocks performed for treatment of chronic pelvic/perineal pain. Updated references.
55. Nilotinib Capsules (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 Danziten tablets.
56. Nivolumab products (Opdivo, Opdivo Qvantig)	09-J2000-33	Review and revision to guideline; consisting of including Opdualag Qvantig and updating dosing, coding, and references.
57. Noncontact Normothermic Wound Therapy	09-E0000-42	Review: Position statement maintained; references updated.
58. Obeticholic Acid (Ocaliva) Tablet	09-J2000-65	
59. Orthopedic Applications of Stem-Cell Therapy	02-38240-02	Scheduled review. Revised description, maintained position statement and updated references.
60. Pembrolizumab (Keytruda) Injection	09-J2000-22	Review and revision to guideline; including updating dosing and references.
61. Pemetrexed (Alimta, Axtle, Pemfexy, Pemrydi RTU) IV	09-J1000-01	Review and revision to guideline; updated position statement, coding, references.
62. Physical Therapy (PT) and Occupational Therapy (OT)	01-97000-01	Scheduled review. Maintained position statement and updated references.

63. Plugs for Fistula Repair	02-45000-02	Review: Position statement maintained, and references updated.
64. Positron Emission Tomography (PET) Oncologic Applications	04-78000-17	Review; no change in position statement. Updated references.
65. Preventive Services	01-99385-03	Update; no change in position statement. Updated references; Code update; added 96041.
66. Remestemcel-I-rknd (Ryoncil) Infusion	09-J5000-14	New Medical Coverage Guideline.
67. SARS-CoV-2 (COVID-19) Testing	09-J4000-73	Review and revision to guideline; consisting of updating references.
68. Seladelpar (Livdelzi) Capsule	09-J5000-02	Review and revision to the guideline consisting of updating the position statement to remove documentation requirements and allow prescribing in consultation with a gastroenterologist or hepatologist.
69. Speech Therapy Services	01-92506-01	Scheduled review. Maintained position statement, revised program exceptions, and updated references.
70. Transanal Endoscopic Microsurgery	02-45000-01	Review: Position statements maintained, and references updated.

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 HCl (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
Ivosidenib (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).

[Guide to Clinical Preventive Services](#) (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.