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: 4/15/2024

New and Revised MCGs:	MCG Number	Update
1. Computerized Dynamic Posturography	01-92502-12	Review; no change in position statement. Updated references.
2. Outpatient Medical Nutrition Therapy	01-99000-05	Review: position statement maintained; description and references updated.
3. Hyperbaric Oxygen Therapy (Systemic & Topical)	01-99180-01	Review: Position statements maintained; program exception and references updated.
4. Ductal Lavage and Suction Collection Systems	02-10000-14	Review: Position statement maintained; description and references updated.
5. Breast Ductoscopy	02-10000-19	Review: Position statement maintained; description and references updated.
6. Mastectomy for Gynecomastia	02-12000-14	Review; no change in position statement. Updated references.
7. Cervical Spine Surgery	02-20000-45	Scheduled review. Revised description, maintained position statement and updated references.
8. Partial Left Ventriculectomy and Surgical Ventricular Restoration	02-33000-18	Scheduled review. Revised description, maintained position statement and updated references.

9. Neurolysis, Ablation	02-61000-34	Scheduled review. Revised description, maintained position statement, and updated references.
10. Computed Tomography Angiography (CTA) Brain (Head)	04-70450-05	Review; maintain position statements. Updated program exception and references.
11. Computed Tomography Angiography (CTA) Neck	04-70450-06	Review; maintain position statements. Updated program exception and references.
12. Computed Tomography Angiography (CTA) Upper Extremity	04-70450-08	Review; no change in position statement. Updated program exception and references.
13. Computed Tomography Angiography (CTA) Lower Extremity	04-70450-09	Review; no change in position statement. Updated program exception and references.
14. Magnetic Resonance Cholangiopancreatography (MRCP)	04-70540-24	Review; maintain position statements. Updated references.
15. Magnetic Resonance Imaging Bone Marrow	04-70540-25	Review; maintain position statements. Updated references.
16. Magnetic Resonance Imaging (MRI) Chest (Thorax)	04-70540-26	Review; no change in position statement. Updated program exception and references.
17. Multiple Gated Acquisition Scan (MUGA)	04-78000-21	Review; no change in position statement. Updated program references.
18. Tumor/Genetic Markers	05-86000-22	Investigational test list, coding, and references updated.
19. ProThelial for the Treatment of Oral Mucositis	09-00000-01	Review: position statement maintained; references updated.
20. Electrostimulation and Electromagnetic Therapy for Treating Wounds	09-E0000-43	Review: Position statements, coding, and references updated.

21. Enteral Formulas	09-J0000-61	Scheduled review. Revised description, maintained position statement and updated references.
22. Drugs and Biologics without Medical Coverage Guideline	09-J0000-68	Revision to guideline; updated position statement to require documentation from the medical record for Xiaflex.
23. Trastuzumab (Herceptin, biosimilars) and Trastuzumab and hyaluronidase-oysk (Herceptin Hylecta) Injection	09-J0000-86	Review and revision; Updated description, position statement, references.
24. Granisetron (Sustol) injection	09-J0000-97	Review and revision to guideline; consisting of updating Table 1 (Emetic potential of neoplastic agents) and references.
25. Abiraterone Acetate (Yonsa, Zytiga) Tablets	09-J1000-36	Review and revision to guideline consisting of updating the position statement, billing/coding, and references.
26. Pertuzumab (Perjeta) Injection	09-J1000-75	Review and revision to guidelines; updated coding, references.
27. Eribulin Mesylate (Halaven) Injection	09-J1000-76	Review and revision; updated position statement, references.
28. Ado-trastuzumab emtansine (Kadcyla)	09-J1000-90	Review and revision to guideline; updated position statement and references.
29. Canakinumab (Ilaris) Injection	09-J2000-03	Revision to guideline; consisting of updating references.
30. Rilonacept (Arcalyst) Injection	09-J2000-04	Review and revision of the guideline, consisting of revising the list of biologic agents not permitted as concomitant therapy within the position statement and updating the references.
31. Obinutuzumab (Gazyva) Injection	09-J2000-07	Revision to guideline consisting of updating the description, position statement, and references. For follicular lymphoma, added obinutuzumab + zanubrutinib (Brukinsa) as a third-line or later therapy based on

		updated NCCN guidelines and new FDA-approved indication for Brukinsa.
32. Daratumumab (Darzalex) Infusion and Daratumumab-Hyaluronidase-fihj (Darzalex Faspro) Injection	09-J2000-49	Revision to guidelines consisting of updating the description section, position statement, billing/coding, and references based on updated NCCN guidelines for MM, pediatric ALL, and SLCA.
33. Aprepitant injectable therapy (Cinvanti)	09-J2000-60	Review and revision to guideline; consisting of updating Table 1 (Emetic potential of neoplastic agents) and references.
34. Fosnetupitant-Palonosetron (Akynzeo) IV	09-J3000-01	Review and revision to guideline; consisting of updating Table 1 (Emetic potential of neoplastic agents) and references.
35. Emapalumab-lzsg (Gamifant) IV	09-J3000-24	Review and revision to guideline; consisting of updating the position statement.
36. Pegloticase (Krystexxa) Infusion	09-J3000-29	Review and revision to guideline consisting of updating the position statement and references. Revised diagnostic criteria and added specialist prescriber requirement.
37. Brexanolone (Zulresso) IV Infusion	09-J3000-36	Review and revision to guideline consisting of revising the position statement to exclude zuranolone use with brexanolone and updating the references.
38. Esketamine (Spravato) Nasal Spray	09-J3000-37	Review and revision of the guideline consisting of revising warnings and precautions to include respiratory depression and updating the references.
39. Step Therapy Requirements for Medicare Outpatient (Part B) Medications	09-J3000-39	Review and revision to guidelines, consisting of addition of non-preferred drugs for ST programs: Avzivi [oncology]; Ryzneuta [colony stimulating factors].
40. Fam-Trastuzumab Deruxtecan-nxki (Enhertu)	09-J3000-58	Review and revision; updated position statement, coding, references.

41. Teprotumumab (Tepezza) Infusion	09-J3000-64	Review and revision to guideline consisting of updating the description section, position statement, precautions, and references.
42. Pertuzumab, Trastuzumab, Hyaluronidase-zzxf (Phesgo)	09-J3000-75	Review and revision to guidelines; updated references.
43. Sacituzumab Govitecan-hziy (Trodelvy)	09-J3000-76	Review and revision of guideline; updated position statement per NCCN, coding, and references.
44. Margetuximab-cmkb (Margenza)	09-J3000- 88	Review and revision to guideline consisting of updating position statement and references.
45. Lumasiran (Oxlumo) Injection	09-J3000-91	Review and revision to guideline; consisting of updating the position statement to include use is not in combination with nedosiran.
46. Foot Care Services	09-M0101-01	Scheduled review. Revised description, maintained position statement and updated references.

What's New: 4/1/2024

New and Revised MCGs:	MCG Number	Update
1. Abrocitinib (Cibinqo) Tablets	09-J4000-27	Revision to guidelines consisting of updating the position statement. The requirements for prior use of a systemic immunosuppressant, Adbry, Dupixent, and Rinvoq for members with atopic dermatitis were removed.
2. ADAMTS13, recombinant-krhn (Adzynma) IV Infusion	09-J4000-75	Revision: Addition of HCPCS code C9167.
3. Avacincaptad pegol (Izervay) intravitreal injection	09-J4000-65	Revision: Added HCPCS code J2782 and deleted codes C9162 and J3490.

4. Bimekizumab-bkzx (Bimzelx) Injection	09-J4000-70	New Medical Coverage Guideline.
5. Bio-Engineered Skin and Soft Tissue Substitutes, Amniotic Membrane and Amniotic Fluid	02-10000-11	Quarterly CPT/HCPCS coding update. Codes A2026, Q4305-Q4310 added; deleted Q4244.
6. Biofeedback	01-90900-01	Quarterly CPT/HCPCS coding update. Added S9002.
7. Blood Glucose Monitors and Supplies	09-E0000-14	Quarterly CPT/HCPCS coding update. Added A4271, E2104.
8. Botulinum Toxins	09-J0000-29	Revision: Added HCPCS code J0589 and deleted codes C9160 and J3590. Letybo added as a cosmetic-use only botulinum toxin.
9. Buprenorphine HCl (Probuphine) Subdermal Implant and Buprenorphine (Brixadi, Sublocade) Subcutaneous Injection	09-J2000-68	Revision: Added HCPCS codes J0577 and J0578 and deleted code J0576.
10. Cantharidin (Ycanth)	09-J4000-68	Revision: Added HCPCS code J7354 and deleted codes C9164 and J3490.
11. Dupilumab (Dupixent) Injection	09-J2000-80	Revision to guideline consisting of updating the description section, position statement, dosage/administration, precautions, and references. Updated with expanded FDA-approved age for the treatment of eosinophilic esophagitis (EoE) and removal of the step requirement of a systemic immunosuppressant for AD (based on new AD guidelines).
12. Elranatamab-bcmm (Elrexfio) Subcutaneous Injection	09-J4000-64	Revision: Added HCPCS code J1323 and deleted codes C9165 and J9999.
13. Enzyme Replacement Therapy for Pompe Disease	09-J4000-06	Revision to guideline; updated position statement, dosing/administration, coding, references.
14. Eplontersen (Wainua)	09-J4000-77	New Medical Coverage Guideline.
15. Etrasimod (Velsipity) Tablet	09-J4000-72	New Medical Coverage Guideline.

16. Exagamglogene autotemcel (Casgevy) suspension for IV infusion	09-J4000-82	New Medical Coverage Guideline.
17. Genetic Testing	05-82000-28	Quarterly CPT/HCPCS coding update. Code 0449U added.
18. Granulocyte Colony Stimulating Factors	09-J0000-62	Review and revision to guideline; consisting of updating the position statement to include Ryzneuta and Udenyca on-body injector and updating indications for eflapegrastim-xnst (Rolvedon).
19. Investigational Services	09-A0000-03	Quarterly CPT/HCPCS coding update. Added A4593, A4594, E0738, E0739.
20. Iptacopan (Fabhalta) Capsules	09-J4000-80	New Medical Coverage Guideline.
21. Lifileucel (Amtagvi) suspension for IV infusion	09-J4000-81	New Medical Coverage Guideline.
22. Lovotibeglogene autotemcel (Lyfgenia) suspension for IV infusion	09-J4000-83	New Medical Coverage Guideline.
23. Mirikizumab-mrkz (Omvoh®) Injection and Infusion	09-J4000-71	New Medical Coverage Guideline.
24. Nedosiran Sodium (Rivfloza) SQ Injection	09-J4000-79	New Medical Coverage Guideline.
25. New To Market Program	09-J4000-30	Removed Casgevy (exagamglogene autotemcel), Lyfgenia (lovotibeglogene autotemcel), Omvoh (mirikizumab-mrkz), Pombiliti (cipaglucosidase alfa-atga), Rivfloza (nedosiran), and Roctavian (valoctocogene roxaparvovec-rvox) from the drug list.
26. Oral Oncology Medications	09-J3000-65	Review and revision to guideline; addition of Augtyro capsules, Fruzaqla capsules, Iwilfin tablets, Ogsiveo tablets, Phyrago tablets, and Truqap tablets.
27. Oral Therapy for Gaucher and Pompe Disease	09-J0000-76	Review and revision to guideline; consisting of updating position statement, dosage/administration, and references.

28. Positive Pressure Ventilation	09-E0000-55	Quarterly CPT/HCPCS update. Code E0468 added.
29. Pozelimab-bbfg (Veopoz)	09-J4000-67	Revision: Added HCPCS code J9376 and deleted code J3590.
30. Prosthetics	09-L0000-05	Quarterly CPT/HCPCS coding update. Added L5841.
31. Secukinumab (Cosentyx) Injection and Infusion	09-J2000-30	Revision: Added HCPCS code C9166.
32. Talquetamab-tgvs (Talvey) Subcutaneous Injection	09-J4000-63	Revision: Added HCPCS code J3055 and deleted codes C9163 and J9999.
33. Tocilizumab (Actemra) Injection and Infusion and tocilizumab-bavi (Tofidence) Infusion	09-J1000-21	Revision: Added HCPCS code Q5133.
34. Tralokinumab-ldrm (Adbry) Injection	09-J4000-20	Revision to guideline consisting of updating the description section, position statement, dosage/administration, and references. Updated with expanded FDA-approved age for the treatment of atopic dermatitis (AD) and removal of the step requirement of a systemic immunosuppressant for AD (based on new AD guidelines).
35. Tumor/Genetic Markers	05-86000-22	Quarterly CPT/HCPCS coding update: Code 0445U added.
36. Valoctocogene Roxaparvovec-rvox (Roctavian)	09-J4000-62	New Medical Coverage Guideline.
37. Vamorolone (Agamree) Oral Solution	09-J4000-76	New Medical Coverage Guideline.
38. Vascular Endothelial Growth Factor Inhibitors for Ocular Neovascularization	09-J1000-78	Revision: Added HCPCS code J0177 and deleted codes C9161 and J3590.
39. Vedolizumab (Entyvio) Injection and Infusion	09-J2000-18	Revision to guideline consisting of updating the position statement regarding continuation of therapy in members not previously approved by Florida Blue.
40. Wheelchairs and Wheelchair Accessories	09-E0000-35	Quarterly CPT/HCPCS coding update. Added E2298. Deleted E2300.

41.	Zilucoplan (Zilbrysq) Subcutaneous Injection	09-J4000-78	New Medical Coverage Guideline.
42.	Zuranolone (Zurzuvae) Capsule	09-J4000-74	New Medical Coverage Guideline.

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

Generic/Brand	MCG Number
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

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.