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What's New: 9/15/2024

New and Revised MCGs:	MCG Number	Update
1. Autologous Chondrocyte Implantation (ACI)	02-20000-17	Scheduled review. Revised description, maintained position statement and updated references.
2. Bio-Engineered Skin and Soft Tissue Substitutes, Amniotic Membrane and Amniotic Fluid	02-10000-11	Revision: Collagen dressing position statements added; coding, reimbursement, and references updated.
3. Botulinum Toxins	09-J0000-29	Revision: Added ICD-10 codes G51.31 – G51.39.
4. Bronchial Thermoplasty	02-30000-12	Review; no change in position statement. Updated references.
5. Cenegermin-bkbj (Oxervate)	09-J3000-15	Review and revision to guideline consisting of revising the position statement approval duration to 12 weeks to allow for the 8-week treatment regimen.
6. Cochlear Implants	02-69000-03	Scheduled review. Maintained position statement and updated references.

7. Complications of Pregnancy	03-59000-04	Review; no change in position statement. Updated references.
8. Computer Assisted Surgical Navigation	02-99221-14	Review; no change in position statement. Updated references.
9. Crovalimab (Piasky)	09-J4000-95	New Medical Coverage Guideline.
10. Cryoablation of Liver Tumors	02-40000-22	Scheduled review. Revised description, maintained position statement, and updated references.
11. Daratumumab (Darzalex) Infusion and Daratumumab-Hyaluronidase-fihj (Darzalex Faspro) Injection	09-J2000-49	Revision to guidelines consisting of updating the description section, position statement, dosage/administration, and references. The FDA approved a new MM regimen for Darzalex Faspro in combination with bortezomib, lenalidomide, and dexamethasone for induction and consolidation in newly diagnosed MM patients who are eligible for ASCT. The FDA-approved regimen is based on 4-week cycles.
12. Diabetic Self-Management Training and Educational Supplies	01-99000-02	Scheduled review. Revised description, maintained position statement and updated references.
13. Donanemab-azbt (Kisunla) intravenous infusion	09-J4000-94	New Medical Coverage Guideline.
14. Donislecel (Lantidra) Allogenic Islet Cell Transplant	09-J4000-58	Review and revision of the guideline to update the position statement for conditions incompatible for transplant and removing the requirement for GLP-1 receptor agonist as concomitant therapy, adding billing code C9399, and updating references.
15. Drugs and Biologics without Medical Coverage Guideline	09-J0000-68	Revision to guideline; added Anktiva, Imdelltra, and Rytelo to table 1.

16. Eculizumab (Soliris) Injection	09-J1000-17	Review and revision to guideline; consisting of updating the the position statement to revise the step for paroxysmal nocturnal hemoglobinuria and updating agents not to be used in combination.
17. Edaravone (Radicava)	09-J2000-82	Revision to guideline; updated position statement.
18. Epcoritamab-bysp (Epkiny) SQ Injection	09-J4000-61	Review and revision to guideline consisting of revising the position statement and dosing/administration section to include the new FDA approved indication for relapsed or refractory follicular lymphoma and its associated dosing, adding billing codes, and updating references.
19. Evinacumab-dgnb (Evkeeza) Infusion	09-J3000-99	Review and revision to guideline consisting of updating the position statement and references. Updated the HoFH diagnosis requirements and added age limits for when certain prerequisite lipid lowering therapy is required.
20. Fidanacogene Elaparvovec (Beqvez)	09-J4000-92	New Medical Coverage Guideline.
21. Glofitamab-gxbl (Columvi) IV Infusion	09-J4000-60	Review and revision to guideline consisting of updating references.
22. Hospital Beds and Accessories	09-E0000-12	Review: Position statements maintained.
23. Lecanemab-irmb (Legembi) intravenous infusion	09-J4000-41	Review and revision to the guideline consisting of revising the Position Statement to specify that baseline assessments should be performed within the last 6 months and to not allow concomitant therapy with donanemab-azbt (Kisunla).

24. Lifileucel (Amtagvi) suspension for IV infusion	09-J4000-81	Update to the position statement to clarify the IL-2 (aldesleukin) dosing of 600,000 IU/kg intravenously for a maximum of 6 total doses within 4 days after the lifileucel (Amtagvi) infusion.
25. Magnetic Resonance - Guided High Intensity Focused Ultrasound Ablation	02-56000-27	Review; no change to position statement. Updated references.
26. Magnetic Resonance Imaging (MRI) Spine (Cervical, Thoracic, Lumbar)	04-70540-17	Revised preoperative and post operative evaluation/planning.
27. Maralixibat (Livmarli)	09-J4000-10	Revision to guidelines consisting of updates to the description, position statement, dosage/administration, precautions, and references based on the expanded FDA-approved age for PFIC and new 19 mg/mL oral solution concentration.
28. Medical & Surgical Management of Sleep Apnea, Snoring, and Other Conditions of the Soft Palate and Nasal Passages	02-40000-16	Review: HNS position statements, description, and references updated.
29. New-To-Market Program for Medical Benefit Medications	09-J4000-30	Review and revision of guideline with updates to the description section, position statement, and billing/coding. Expanded the scope of the program to include any medical benefit medication. Removed Beqvez (fidanacogene elaparvovec-dzkt), Kisunla (donanemab-azbt) and Piasky (crovalimab-akkz) from the drug list.
30. Orthognathic Surgery	02-12000-17	Revision. Changed coverage designation for genioplasty from “does not meet the definition of medical necessity” to “non-covered”.
31. Oxygen	09-E0400-00	Review: Informational note on airline travel added; program exception section and references updated.

32. Panniculectomy and Abdominoplasty	02-12000-16	Review; no change in position statement.
33. Pelvic Floor Stimulation as a Treatment of Incontinence	01-97000-06	Scheduled review. Maintained position statement and updated references.
34. Percutaneous Electrical Nerve Stimulation (PENS)	02-61000-03	Revision. Revised description, maintained position statement and updated references.
35. Percutaneous Left Atrial Appendage Closure Devices for Stroke Prevention in Atrial Fibrillation	02-33000-36	Scheduled review. Maintained position statement and updated references.
36. Physical Therapy (PT) and Occupational Therapy (OT)	01-97000-01	Revision. Revised description, added coverage statement for AposTherapy®, and updated references.
37. Positive Airway Pressure Devices	09-E0000-21	Review: Position statements maintained and references updated.
38. Positron Emission Tomography (PET) Miscellaneous Applications	04-78000-18	Review; added statement for anti-amyloid drug. Updated references.
39. Prophylactic Mastectomy	02-12000-15	Review; no change to position statement. Updated references.
40. Reduction Mammoplasty	02-12000-11	Review; no change to position statement. Updated references.
41. Resmetirom (Rezdiffra) tablets	09-J4000-85	Review and revision to guideline consisting of revising the position statement to require documentation of the FIB-4 score, allow for non-invasive liver tests as an alternative to liver biopsy, and extension of the initial approval duration to 1 year.
42. Selective Internal Radiation Therapy	04-77260-21	Review; no change to position statement. Updated references.

43. Sleep Testing	01-95828-01	Review: Position statements, description, and references updated.
44. Speech Generating Devices	09-E0000-51	Scheduled review. Maintained position statement and updated references.
45. Technologies for the Evaluation of Malignant Melanoma	01-96900-03	Review: Position statement maintained; description and references updated.
46. Tofersen (Qalsody) Intrathecal Injection	09-J4000-59	Review and revision to guideline consisting of updating the position statement to allow prescribing of tofersen (Qalsody) by, or in consultation with, a neurologist or neuromuscular specialist but limiting diagnosis to a specialist, requiring laboratory documentation for the genetic test, and updating references.
47. Transcatheter Mitral Valve Repair/Replacement and Transcatheter Tricuspid Valve Repair	02-33000-35	Review: Position statements, title, description, coding, and references updated.
48. Treatment of Hyperhidrosis	01-94010-08	Scheduled review. Revised description, added CPT 64818, maintained position statement and updated references.
49. Tumor Treating Fields Therapy	02-61000-10	Scheduled review. Maintained position statement and updated references.
50. Tumor/Genetic Markers	05-86000-22	Revision: codes 80145, 80230, 80280 removed.
51. Valbenazine (Ingrezza, Ingrezza Sprinkle)	09-J2000-81	Review and revision to guideline; consisting of updating the position statement to include Ingrezza Sprinkle capsules.
52. Wheelchairs and Wheelchair Accessories	09-E0000-35	Scheduled review. Maintained position statement, revised Medicare Advantage program exception, and updated references.

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.