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What's New: 12/15/2024

New and Revised MCGs:	MCG Number	Update
1. Abortion	03-59800-01	Review; no change in position statement.
2. Afamelanotide (Scenesse) Implant	09-J4000-38	Review and revision of the guideline, consisting of revising the position statement to require only laboratory documentation for genetic testing, adding hypersensitivity reactions to the warnings/precautions and contraindication sections, and updating the references.
3. Budesonide (Tarpeyo)	09-J4000-14	Revision to guideline; updated position statement
4. Crovalimab (Piasky)	09-J4000-95	Review and revision to guideline; consisting of updating the position statement for paroxysmal nocturnal hemoglobinuria.
5. Dopamine Transporter Imaging with Single-Photon Emission Computed Tomography	04-78000-23	Review; no change to position statement. Updated references.
6. Eculizumab (Soliris) Injection	09-J1000-17	Revision to guideline; consisting of updating position statement for

		paroxysmal nocturnal hemoglobinuria and updating agents used in combination.	
7.	Genetic Testing	05-82000-28	Revision: Genetic testing for apolipoprotein E (APOE) gene in Alzheimer disease position statement revised. IsoPSA test reviewed; description, coding, and references updated.
8.	Ingestible pH and Pressure Capsule	01-91000-08	Review; no change in position statement. Updated references.
9.	Iptacopan (Fabhalta) Capsules	09-J4000-80	Review and revision to guideline; updated position statement to include primary immunoglobulin A nephropathy (IgAN) revising criteria for paroxysmal nocturnal hemoglobinuria.
10.	Isatuximab-irfc (Sarclisa) Infusion	09-J3000-67	Revision to guidelines consisting of updating the description, position statement, dosage/administration, precautions, and references based on a new FDA-approved indication and NCCN recommendations.
11.	Lanreotide (Somatuline Depot) Injection	09-J1000-20	Review and revision to guideline; consisting of updating the position statement to require step through J1930.
12.	Microwave Tumor Ablation Other Than Liver Tumors	02-99221-18	Review; no change in position statement. Updated references.
13.	Nerve Conduction Studies, F-wave Studies, H-reflex Studies	01-95805-02	Review; no change in position statement. Updated references.
14.	Ocrelizumab (Ocrevus, Ocrevus Zunovo) Infusion	09-J2000-78	Review and revision to guideline; consisting of updating the position statement to include Ocrevus Zunovo.
15.	Olipudase Alfa-rpcp (Xenpozyme)	09-J4000-34	Review and revision to guideline; updated coding and references.

16. <u>Oxaveloxolone (Skyclarys) Oral Capsule</u>	09-J4000-49	Review and revision of the guideline, consisting of revising the position statement to require only laboratory documentation for genetic testing and updating the references.
17. <u>Oxybate Oral Solutions (Sodium Oxybate, Xyrem, and Xywav) and Suspension (Lumryz)</u>	09-J1000-06	Revision to guideline consisting of updating the description, position statement, dosage/administration, precautions and references due to the narcolepsy indication for Lumryz being approved by the FDA to include patients 7 years of age and older.
18. <u>Percutaneous Electrical Nerve Stimulation (PENS)</u>	02-61000-03	Revision. Updated age criteria for PENFS with IB-STIM®. Updated references.
19. <u>Pyrimethamine (Daraprim)</u>	09-J2000-48	Review and revision to guideline consisting of updating position statement and references
20. <u>Ravulizumab (Ultomiris) IV</u>	09-J3000-26	Revision to guidelines; consisting of updating the position statement for agents used in combination for PNH.
21. <u>Reconstructive Surgery/ Cosmetic Surgery</u>	02-12000-01	Review; no change to position statement. Updated references.
22. <u>Site of Care Guideline for Select Specialty Medications</u>	09-J3000-46	Revision to guideline consisting of updating the position statement, billing/coding, and related guidelines based on the addition of Ocrevus Zunovo.
23. <u>Sparsentan (Filspari)</u>	09-J4000-48	Revision to guideline; updated position statement.
24. <u>Tumor/Genetic Markers</u>	05-86000-22	Revision: Alzheimer disease CSF biomarker testing statement updated; multianalyte assays for chronic liver disease statements maintained; investigational test list, coding, and references updated.

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| 25. <u>Velmanase alfa-tycv (Lamzede) intravenous infusion</u> | 09-J4000-50 | Review and revision of the guideline, consisting of revising the position statement to require only laboratory documentation for genetic testing and updating the references. |
| 26. <u>Wireless Capsule Endoscopy</u> | 01-91000-05 | Review; Add statement for magnetic capsule endoscopy. 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.