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What's New: 1/15/2025

New and Revised MCGs:	MCG Number	Update
1. Allogeneic Processed Thymus Tissue_agdc (Rethymic)	09-J4000-11	Review and revision to guidelines consisting of updating the references.
2. Asfotase alfa (Strensiq)	09-J2000-58	Review and revision to guideline; position statement, references.
3. Avatrombopag (Doptelet)	09-J3000-02	Review and revision to guideline including updating the position statement for risk of bleeding.
4. Botulinum Toxins	09-J0000-29	Review and revision to guideline consisting of updating the description, position statement, billing/coding, and references. For chronic migraine prophylaxis, limited the required step therapy to CGRP inhibitor treatment only. Added new indication for large, complex ventral hernia repair. For essential tremor, modified the step requirement to a single step. Added a specialist requirement for all indications stating that the botulinum toxin requested is being prescribed by, or in consultation with, a provider specialized in treating the member's condition.

5. <u>Burosumab (Crysvita)</u>	09-J2000-99	Review and revision; updated references.
6. <u>Donanemab-azbt (Kisunla) intravenous infusion</u>	09-J4000-94	Review and revision to guidelines consisting of revising the position statement to require lecanemab (Leqembi) therapy prior to donanemab (Kisunla) therapy for AD patients with mild cognitive impairment or mild dementia stage of the disease and updating references.
7. <u>Edaravone (Radicava)</u>	09-J2000-82	Review and revision to guidelines consisting of updating the references.
8. <u>Eladocagene exuparvovec-tneq (Kebilidi) Suspension for Intrapataminal Infusion</u>	09-J5000-06	New Medical Coverage Guideline – Eladocagene exuparvovec-tneq (Kebilidi), an adeno-associated virus (AAV) vector-based gene therapy, for the treatment of adult and pediatric patients with genetically confirmed aromatic L-amino acid decarboxylase (AADC) deficiency.
9. <u>Eltrombopag (Promacta, Alvaiz)</u>	09-J1000-13	Review and revision to guideline; consisting of updating MCG to include Alvaiz and included risk of bleeding for Promacta.
10. <u>Fosdenopterin Hydrobromide (Nulibry) IV Infusion</u>	09-J3000-95	Review and revision to guideline; updated references.
11. <u>Fostamatinib (Tavalisse)</u>	09-J3000-00	Review and revision to guideline consisting of updating the position statement for risk of bleeding.
12. <u>Immune Globulin Therapy</u>	09-J0000-06	Review and revision to guideline; consisting of updating the position statement to include Yimmugo, updating acquired secondary hypogammaglobulinemia, and updating the use for chronic ITP, immune checkpoint inhibitor toxicity, CAR-T cell

		induced reactions, and refractory myasthenia gravis.
13. Irinotecan Liposome Injection (Onivyde)	09-J2000-52	Review and revision to guideline consisting of updating references.
14. Luspatercept-aamt (Reblozyl)	09-J3000-61	Review and revision to guideline consisting of updating the description section (NCCN info), position statement, billing/coding, and references. Added new indication of myelofibrosis-associated symptomatic anemia per NCCN. Added an allowance that member's with MDS or MDS/MPN-RS-T can qualify for treatment prior to transfusion when certain requirements are met.
15. New-To-Market Program for Medical Benefit Medications	09-J4000-30	Removed Posfrea (palonosetron) and Kebilidi (eladocagene exuparvovec-tneq) from the drug list.
16. Nusinersen (Spinraza)	09-J2000-70	Review and revision to guideline; updating references.
17. Omadacycline (Nuzyra) Tablet	09-J3000-72	Review and revision to guidelines consisting of updating the description section, position statement, billing/coding, and references. Added new indication of outpatient treatment of a rapidly growing, nontuberculous mycobacteria (NTM) infection. Added an infectious disease specialist requirement to all non-CABP or non-ABSSSI infections.
18. Onasemnogene abeparvovec (Zolgensma)	09-J3000-30	Review of guideline; Updated references.
19. Palonosetron Hydrochloride (Posfrea)	09-J0000-87	Policy updated to include Posfrea.
20. Riluzole (Tiglutik, Exservan)	09-J3000-38	Review and revision to guidelines consisting of updating the references.

21. Risdiplam (Evrysdi)	09-J3000-77	Review and revision to guideline; Updated references.
22. Rituximab Products	09-J0000-59	Review and revision to guideline; consisting of updating to include Epstein Barr virus induced HLH, minimal change disease, and updated ITP for risk of bleeding.
23. Romiplostim Injection (Nplate)	09-J0000-88	Review and revision to guideline; consisting of updating the initial dosing titration and included risk of bleeding.
24. Triheptanoin (Dojolvi) Oral Liquid	09-J3000-87	Review and revision to guidelines consisting of updating the 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.