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: 6/15/2025

New and Revised MCGs:	MCG Number	Update
1. Clotting Factors and Coagulant Blood Products	09-J0000-34	Revision to position statement.
2. Computed Tomography to Detect Coronary Artery Calcification	04-70450-02	Review; no change in position statement.
3. Crovalimab (Piasky)	09-J4000-95	Review and revision to guideline; consisting of updating the step in the position statement for paroxysmal nocturnal hemoglobinuria.
4. Danicopan (Voydeya)	09-J4000-88	Review and revision to guideline; consisting of including use with eculizumab biosimilars and updating agents not to be used in combination.
5. Datopotamab Deruxtecan (Datroway) IV Infusion	09-J5000-19	New Medical Coverage Guideline
6. Drugs and Biologics without Medical Coverage Guideline	09-J0000-68	Revision to guideline; added Onapgo and Chenodal and removed Chemet from table 1
7. Eculizumab (Soliris) Injection	09-J1000-17	Review and revision to guideline; consisting of updating the the position statement to include biosimilar agents Epysqli and Bkemv. Updated dosing for

		members less than 40 kilograms for generalized Myasthenia Gravis and aHUS.
8. **Evoked Potentials, Intraoperative Neurophysiologic Monitoring, and Quantitative Electroencephalography (QEEG)**	01-95805-13	Review: Position statements maintained and references updated.
9. **Exagamglogene autotemcel (Casgevy) suspension for IV infusion**	09-J4000-82	Review and revision of guideline consisting of revising the position statement to list examples of genotypes, allowing VOC/VOEs to present to a medical facility, assessment of LVEF for potential cardiac iron overload, defining "previous gene therapy" as those specifically for SCD and TDT, removing cell count requirements, clarifying parameters for liver disease assessment such as direct bilirubin 2xULN and imaging tests such as MRI, ultrasound and CT, outlining the types of active infections, and requesting lab and imaging documentation to be within the last 6 months.
10. **In Vitro Chemoresistance and Chemosensitivity Assays**	05-86000-11	Review: Position statements maintained; description and coding updated.
11. **Inclisiran (Leqvio) Injection**	09-J4000-21	Review and revision to guidelines consisting of updates to the position statement and references. Simplified the criteria for the 10-year ASCVD risk ≥20% indications, and the criteria for statin intolerance.
12. **Inebilizumab (Uplizna) Injection**	09-J3000-73	Review and revision to guideline; consisting of including Immunoglobulin G4-related disease (IgG4-RD) to the position statement.
13. **Infertility**	02-56000-24	Review; no change in position statement. Updated references.

14. **Investigational Services**	09-A0000-03	Deleted code (31242, 31243) (refer to policy 02-31000-03).
15. **Iptacopan (Fabhalta) Capsules**	09-J4000-80	Review and revision to guideline; updated position statement to include complement 3 glomerulopathy (C3G).
16. **Irreversible Electroporation (IRE)**	02-40000-26	Scheduled review. Updated references, revised description and maintained position statement (added specific indication of prostate cancer).
17. **Knee Arthroscopy and Open, Non-Arthroplasty Knee Repair**	02-20000-65	Scheduled review. Revised description, maintained position statement and updated references.
18. **Lovotibeglogene autotemcel (Lyfgenia) suspension for IV infusion**	09-J4000-83	Review and revision of guideline consisting of revising the position statement to list examples of genotypes, allowing VOC/VOEs to present to a medical facility such as an ER, defining frequency of VOC/VOEs to be 2 or more in the previous 12 months or 4 or more in the previous 24 months, limiting the HLA-matched family donor requirement to members less than 18 years old, removing cell count requirements, clarifying imaging tests such as MRI, ultrasound and CT for assessment of liver disease, outlining the types of active infections, and requesting lab and imaging documentation to be within the last 6 months.
19. **Magnetic Resonance Imaging of the Breast**	04-70540-09	Review; deleted no history of breast cancer. Updated references.
20. **Maralixibat (Livmarli)**	09-J4000-10	Revision to guidelines consisting of updates to the description, position statement, dosage/administration, and references based on the release of an oral tablet formulation.

21. **Mechanical Stretching Devices for Treatment of Joint Stiffness and Contractures**	09-E0000-47	Review: Position statements maintained; references updated.
22. **Myoelectric Prosthetic and Orthotic Components for the Upper Limb**	09-L0000-07	Review: Position statements maintained; description, coding, and references updated.
23. **New-To-Market Program for Medical Benefit Medications**	09-J4000-30	Removed Bkemv (eculizumab-aeeb) IV infusion and Epysqli (eculizumab-aagh) IV infusion from the drug list.
24. **Oral Oncology Medications**	09-J3000-65	Review and revision to guideline; addition of Gomekli capsules and tablets and Romvimza capsules to Table 1.
25. **Orthognathic Surgery**	02-12000-17	Scheduled review. Revised description, maintained position statement and updated references.
26. **Pegcetacloplan (Empaveli) Infusion**	09-J4000-04	Review and revision to guideline; consisting of updating the agents not to be used in combination and updating references.
27. **Positive Pressure Ventilation**	09-E0000-55	Review: Position statements maintained; program exceptions section and references updated.
28. **Radiation Treatment Delivery and Radiation Treatment Management - Reimbursement Guideline**	04-77260-01	Review; no change to position statement.
29. **Ravulizumab (Ultomiris) Injection**	09-J3000-26	Review and revision to guidelines; consisting of updating the position statement for agents used in combination for covered indications.
30. **Resmetirom (Rezdiffra) tablets**	09-J4000-85	Review and revision to guideline consisting of revising the position statement to clarify treatment of present

		metabolic risk factors and updating references.
31. **Revakinagene taroretcel-lwey (Encelto) Intravitreal Implant**	09-J5000-17	New Medical Coverage Guideline – Revakinagene taroretcel-lwey (Encelto), an allogeneic encapsulated cell-based gene therapy that is intravitreally inserted, for the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel2).
32. **Rozanolixizumab-noli (Rystiggo) Injection**	09-J4000-55	Review and revision to guideline; consisting of updating agents not to be used in combination.
33. **Satralizumab (Enspryng)**	09-J3000-79	Review and revision to guideline; consisting of updating the position statement for agents not used in combination.
34. **Subtalar Arthroereisis**	02-99221-17	Review: Position statement maintained and references updated.
35. **Surgical Ablation for Treatment of Chronic Rhinitis**	02-31000-03	New Medical Coverage Guideline.
36. **Therapeutic Radiology Simulation-Aided Field Setting Reimbursement Guideline**	04-77260-05	Review; no change to position statement.
37. **Therapeutic Radiology Treatment Planning Reimbursement Guideline**	04-77260-04	Review; no change to position statement.
38. **Thoracic and Lumbar Spine Surgery**	02-20000-48	Scheduled review. Maintained position statement and updated references.
39. **Transvaginal Radiofrequency Bladder Neck Suspension and Transurethral Radiofrequency Tissue Remodeling for Urinary Stress Incontinence**	02-50000-16	Review; no change in position statement. Updated references.
40. **Zilucoplan (Zilbrysq) Subcutaneous Injection**	09-J4000-78	Revision to guideline consisting of updating the step requirements in the position statement.

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
Idelalisib (Zydelig)	09-J2000-23
Ivosidenib (Tibsovo)	09-J3000-13
Lapatinib (Tykerb)	09-J1000-47

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
Vemurafenib (Zelboraf)	09-J1000-40
Venetoclax (Venclexta)	09-J2000-64
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.