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What's New: 7/1/2025

New and Revised MCGs:	MCG Number	Update
1. Abatacept (Orencia) Injection and Infusion	09-J0000-67	Revision: Added Selarsdi, Steqeyma and Yesintek among the preferred agents for PsA for Orencia SC.
2. Aprocitentan (Tryvio) Tablets	09-J5000-18	New Medical Coverage Guideline: Aprocitentan (Tryvio) for the treatment of resistant hypertension in combination with at least three antihypertensive medications from different classes at maximally tolerated doses.
3. Atidarsagene autotemcel (Lenmeldy) suspension for IV infusion	09-J4000-84	Revision: Added HCPCS code J3391 and deleted code J3590.
4. Atrasentan (Vanrafia) tablet	09-J5000-20	New Medical Coverage Guideline.
5. Bimekizumab-bkzx (Bimzelx) Injection	09-J4000-70	Revision: Added Selarsdi, Steqeyma and Yesintek among the preferred agents for PS and PsA.
6. Bio-Engineered Skin and Soft Tissue Substitutes, Amniotic Membrane and Amniotic Fluid	02-10000-11	Quarterly CPT/HCPCS coding update. Codes Q4368-Q4382 added.

7. Brodalumab (Siliq) Injection	09-J2000-79	Revision: Added Selarsdi, Steqeyma and Yesintek among the preferred agents for PS.
8. Certolizumab Pegol (Cimzia) Injection	09-J0000-77	Revision: Added Selarsdi, Steqeyma and Yesintek among the preferred agents for CD, PS, and PsA for for self-administered Cimzia.
9. Chenodiol (Ctexli) Tablets	09-J5000-16	New Medical Coverage Guideline: Chenodiol (Ctexli), a bile acid, for the treatment of cerebrotendinous xanthomatosis (CTX) in adults.
10. Chimeric Antigen Receptor (CAR) T-Cell Therapies	09-J3000-94	Revision: Added HCPCS code Q2058 and removed codes C9301 and J9999.
11. **Datopotamab Deruxtecan (Datroway) IV Infusion**	09-J5000-19	Revision: Added HCPCS code C9174.
12. Diazoxide Choline (Vykat XR) Tablet	09-J5000-21	New Medical Coverage Guideline.
13. Docetaxel Products	09-J0000-95	Revision to guideline, updated position statement and coding.
14. Efgartigimod alfa-fcab (Vyvgart, Vyvgart Hytrulo) injection	09-J4000-18	Update to position statement to include Vyvgart Hytrulo prefilled syringe and updated agents not to be used in combination.
15. Etrasimod (Velsipity) Tablet	09-J4000-72	Revision: Added Selarsdi, Steqeyma and Yesintek among the preferred agents for UC.
16. Foscarbidopa-Foslevodopa (Vyalev) subcutaneous infusion	09-J5000-09	Revision: Added HCPCS code J7356 and deleted codes C9399 and J3490.
17. Golimumab (Simponi, Simponi Aria) Injection and Infusion	09-J1000-11	Revision: Added Selarsdi, Steqeyma and Yesintek among the preferred agents for PsA for Simponi.

18. **Gonadotropin Releasing Hormone Analogs and Antagonists**	09-J0000-48	Revision: Revised description of HCPCS code J1954. Cipla product is now Lutrate Depot from Avyxa Pharma.
19. **Implantable Cardioverter Defibrillators/Cardiac Contractility Modulation (CCM) Therapy**	02-33000-34	Quarterly CPT/HCPCS coding update. Codes 0948T, 0949T added.
20. **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.
21. **Infliximab Products [infliximab (Remicade), infliximab-dyyb (Inflectra), infliximab-abda (Renflexis), and infliximab-axxq (Avsola)]**	09-J0000-39	Revision: Added Selarsdi, Steqeyma and Yesintek among the preferred agents for CD and UC for Zymfentra SC.
22. **Injectable Bulking Agents for Treatment of Urinary and Fecal Incontinence**	09-A9000-03	Quarterly CPT/HCPCS coding update. Added 0963T.
23. **Ixekizumab (Taltz) Injection**	09-J2000-62	Revision: Added Selarsdi, Steqeyma and Yesintek among the preferred agents for PS and PsA.
24. **Lebrikizumab-lbkz (Ebglyss) Injection**	09-J5000-00	Revision to guidelines consisting of updates to the description section, position statement, and related guidelines. The step through other biologic agents for atopic dermatitis was removed.
25. **Medical & Surgical Management of Sleep Apnea, Snoring, and Other Conditions of the Soft Palate and Nasal Passages**	02-40000-16	Quarterly CPT/HCPCS coding update. Codes 0964T-0966T added.
26. **Mirikizumab-mrkz (Omvoh®) Injection and Infusion**	09-J4000-71	Revision: Added Selarsdi, Steqeyma and Yesintek among the preferred agents for CD and UC.

27. **Nemolizumab-ilto (Nemluvio) Injection**	09-J4000-99	Revision to guidelines consisting of update to the description section, position statement, dosage/administration, definitions, related guidelines, billing/coding, and references. New indication of moderate-to-severe atopic dermatitis added.
28. **New-To-Market Program for Medical Benefit Medications**	09-J4000-30	Added Bomyntra (denosumab-bnht) and Conexxence (denosumab-bnht) SC injections, and removed Wezlana (ustekinumab-auub), Otulfi (ustekinumab-aauz), Pyzchiva (ustekinumab-ttwe) and Imuldosa (ustekinumab-srlf) SC injections and IV infusions from the drug list. Added HCPCS code for Tepylute.
29. **Nivolumab products (Opdivo, Opdivo Qvantig)**	09-J2000-33	Revision: Added HCPCS code J9289 and removed code J9999.
30. **Omalizumab (Xolair, Omlyclo)**	09-J0000-44	Revision to guideline; updated position statement
31. **Ozanimod (Zeposia) Capsules**	09-J3000-70	Revision: Added Adalimumab-aaty, Adalimumab-adaz, Entyvio SC, Selarsdi, Steqeyma and Yesintek among the preferred agents for UC. New link to the list of biologic immunomodulator agents not permitted as concomitant therapy.
32. **Pemetrexed (Alimta, Axtle, Pemfexy, Pemrydi RTU) IV**	09-J1000-01	Revision: Revised description of HCPCS code J9292.
33. **Preferred Agents Table and Drug List**	09-J9000-01	Revision. The biosimilars of Selarsdi, Steqeyma, and Yesintek added among the preferred self-administered ustekinumab products that also still includes Stelara. The table now only references “ustekinumab product(s)”. Rinvoq added as a Step 1a agent for GCA. For Actemra SC, Tyenne SC is the required Step 1 agent for GCA.

34. **Preventive Services**	01-99385-03	Revision/update. Revised USPSTF recommendation for screening for obesity in children and adolescents 6 years or older. Annual HCPCS code update. Added 90635.
35. **Subcutaneous Prophylactic Therapy for Hemophilia (Non-Clotting Factor)**	09-J5000-12	Revised position statement. Added HCPCS code J7172.
36. **Tolvaptan (Jynarque) Tablet**	09-J3000-09	Review and revision to guideline consisting of revising the position statement to remove documentation requirements, changing kidney function requirements to no stage 5 CKD or dialysis, and expanding specialist prescribers and updating the references.
37. **Ublituximab-xiiy (Briumvi)**	09-J4000-45	Review and revision to guideline; consisting of updating the position statement to remove step requirement.
38. **Upadacitinib Tablets (Rinvoq) and Oral Solution (Rinvoq LQ)**	09-J3000-51	Revision to guideline consisting of updating the description section, position statement, dosage/administration, precautions, billing/coding, and references. New FDA-approved indication for GCA in adults. Rinvoq is a Step 1a agent for GCA.
39. **Ustekinumab Products (Stelara and Biosinilars)**	09-J1000-16	Revision to guideline consisting of updating the description section, position statement, dosage/administration, precautions, billing/coding, and references. Selarsdi, Stelara, Steqeyma and Yesintek are the co-preferred SC and IV ustekinumab products. Unbranded Ustekinumab SC (provider-administered) and IV is also a co-preferred product on the medical benefit only.

What's New: 6/15/2025

New and Revised MCGs:	MCG Number	Update
40. Clotting Factors and Coagulant Blood Products	09-J0000-34	Revision to position statement.
41. Computed Tomography to Detect Coronary Artery Calcification	04-70450-02	Review; no change in position statement.
42. Crovalimab (Piasky)	09-J4000-95	Review and revision to guideline; consisting of updating the step in the position statement for paroxysmal nocturnal hemoglobinuria.
43. 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.
44. Datopotamab Deruxtecan (Datroway) IV Infusion	09-J5000-19	New Medical Coverage Guideline
45. Drugs and Biologics without Medical Coverage Guideline	09-J0000-68	Revision to guideline; added Onapgo and Chenodal and removed Chemet from table 1
46. 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.
47. Evoked Potentials, Intraoperative Neurophysiologic Monitoring, and Quantitative Electroencephalography (QEEG)	01-95805-13	Review: Position statements maintained and references updated.
48. 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.
49. **In Vitro Chemoresistance and Chemosensitivity Assays**	05-86000-11	Review: Position statements maintained; description and coding updated.
50. **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.
51. **Inebilizumab (Uplizna) Injection**	09-J3000-73	Review and revision to guideline; consisting of including Immunoglobulin G4-related disease (IgG4-RD) to the position statement.
52. **Infertility**	02-56000-24	Review; no change in position statement. Updated references.
53. **Investigational Services**	09-A0000-03	Deleted code (31242, 31243) (refer to policy 02-31000-03).
54. **Iptacopan (Fabhalta) Capsules**	09-J4000-80	Review and revision to guideline; updated position statement to include complement 3 glomerulopathy (C3G).
55. **Irreversible Electroporation (IRE)**	02-40000-26	Scheduled review. Updated references, revised description and maintained position statement (added specific indication of prostate cancer).

56. **Knee Arthroscopy and Open, Non-Arthroplasty Knee Repair**	02-20000-65	Scheduled review. Revised description, maintained position statement and updated references.
57. **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.
58. **Magnetic Resonance Imaging of the Breast**	04-70540-09	Review; deleted no history of breast cancer. Updated references.
59. **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.
60. **Mechanical Stretching Devices for Treatment of Joint Stiffness and Contractures**	09-E0000-47	Review: Position statements maintained; references updated.
61. **Myoelectric Prosthetic and Orthotic Components for the Upper Limb**	09-L0000-07	Review: Position statements maintained; description, coding, and references updated.
62. **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.

63. **Oral Oncology Medications**	09-J3000-65	Review and revision to guideline; addition of Gomekli capsules and tablets and Romvimza capsules to Table 1.
64. **Orthognathic Surgery**	02-12000-17	Scheduled review. Revised description, maintained position statement and updated references.
65. **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.
66. **Positive Pressure Ventilation**	09-E0000-55	Review: Position statements maintained; program exceptions section and references updated.
67. **Radiation Treatment Delivery and Radiation Treatment Management - Reimbursement Guideline**	04-77260-01	Review; no change to position statement.
68. **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.
69. **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.
70. **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).
71. **Rozanolixizumab-noli (Rystiggo) Injection**	09-J4000-55	Review and revision to guideline; consisting of updating agents not to be used in combination.

72. **Satralizumab (Enspryng)**	09-J3000-79	Review and revision to guideline; consisting of updating the position statement for agents not used in combination.
73. **Subtalar Arthroereisis**	02-99221-17	Review: Position statement maintained and references updated.
74. **Surgical Ablation for Treatment of Chronic Rhinitis**	02-31000-03	New Medical Coverage Guideline.
75. **Therapeutic Radiology Simulation-Aided Field Setting Reimbursement Guideline**	04-77260-05	Review; no change to position statement.
76. **Therapeutic Radiology Treatment Planning Reimbursement Guideline**	04-77260-04	Review; no change to position statement.
77. **Thoracic and Lumbar Spine Surgery**	02-20000-48	Scheduled review. Maintained position statement and updated references.
78. **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.
79. **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.