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: 5/15/2024

New and Revised MCGs:	MCG Number	Update
1. Agalsidase Beta (Fabrazyme) IV	09-J2000-59	Review and revision to guideline consisting of updating the position statement, precautions, related guidelines, and references. Added that agalsidase beta will NOT be used in combination with pegunigalsidase (Elfabrio).
2. Allogeneic Hematopoietic Cell Transplantation	02-38240-01	Scheduled review. Maintained position statement and updated references.
3. Assays of Genetic Expression in Tumor Tissue as a Technique to Determine Prognosis in Patients with Breast Cancer	05-86000-26	Revision: Position statements and description updated.
4. Auditory and Sensory Integration Training Therapy (AIT)	01-92502-13	Review; no change in position statement. Updated references.
5. Autologous Hematopoietic Cell Transplantation	02-38241-01	Scheduled review. Maintained position statement and updated references.
6. Bio-Engineered Skin and Soft Tissue Substitutes, Amniotic Membrane and Amniotic Fluid	02-10000-11	Review: Position statements, description, coding, reimbursement, and references updated.
7. Cenegermin-bkbj (Oxervate)	09-J3000-15	Review and revision to guideline consisting of updating the references.

8. Cranial Orthosis for Craniosynostoses and Plagiocephaly	09-L0000-02	Review: Position statements maintained; description and references updated.
9. Crizanlizumab-tmca (Adakveo)	09-J3000-56	Review and revision of guideline; Updated position statement and references.
10. Eculizumab (Soliris) Injection	09-J1000-17	Review and revision to guideline; consisting of updating the position statement to revise neuromyelitis optica spectrum disorder and updating agents not to be used in combination.
11. Efgartigimod alfa-fcab (Vyvgart, Vyvgart Hytrulo) injection	09-J4000-18	Revision to guideline consisting of updating the agents not to be used in combination and lab documentation requirements. Update to warnings and references.
12. Elexacaftor-Tezacaftor-Ivacaftor (Trikafta)	09-J3000-53	Review and revision; updated position statement, dosing, references.
13. Elivaldogene autotemcel (Skysona)	09-J4000-33	Revision to guideline consisting of revising the position statement to limit genetic testing results to laboratory documentation and updating references.
14. Excimer Laser Therapy for Treatment of Dermatologic Conditions	02-10000-13	Review: Position statements maintained; description and references updated.
15. Extracorporeal Photopheresis (ECP)	01-90919-02	Scheduled review. Revised description, maintained position statement and updated references.
16. Extracorporeal Shock Wave Therapy in the Treatment of Peyronie's Disease	02-54000-20	Review: Position statement maintained; description and references updated.
17. Functional Neuromuscular Stimulation	09-E0000-54	Position statements maintained.
18. Image-Guided Radiation Therapy	04-77260-19	Review; no change in position statement. Updated references
19. Implantable Cardioverter Defibrillators/Cardiac Contractility Modulation (CCM) Therapy	02-33000-34	Position statements maintained; references updated.

20. Inebilizumab (Uplizna) Injection	09-J3000-73	Review and revision to guideline; consisting of updating the position statement to remove requirement for alternative immunosuppressant therapy.
21. Iptacopan (Fabhalta) Capsules	09-J4000-80	Revision to guideline including updating the vaccination requirement in the position statement.
22. Ivacaftor (Kalydeco) Oral	09-J1000-68	Review and revision to guideline; consisting of updating position statement, dosing, and references.
23. Laboratory Tests Post Transplant and for Heart Failure	05-86000-24	Revision: Description section updated.
24. Laser Vitreolysis	02-65000-14	Position statements maintained.
25. Leniolisib Phosphate (Joenja)	09-J4000-51	Review and revision to guidelines consisting of updates to the position statement and references. The baseline clinical findings requirements for initiation have been revised.
26. Lonafarnib (Zokinvy)	09-J3000-89	Review and revision to guideline; updated references.
27. Lumacaftor Ivacaftor (Orkambi) Capsule	09-J2000-29	Review and revision to guideline; consisting of updating position statement, dosing, and references.
28. Magnetic Resonance Imaging (MRI) Abdomen and Pelvis	04-70540-14	Review; no change in position statement. Updated references.
29. Magnetic Resonance Imaging (MRI) Brain and Head	04-70540-11	Review; no change in position statement. Updated references.
30. Magnetic Resonance Imaging (MRI) Lower Extremity	04-70540-16	Review; no change in position statement. Updated references.
31. Magnetic Resonance Imaging (MRI) Spine (Cervical, Thoracic, Lumbar)	04-70540-17	Review; no change in position statement. Updated references.

32. Magnetic Resonance Imaging (MRI) Upper Extremity	04-70540-15	Review; no change in position statement. Updated references.
33. Magnetic Resonance Spectroscopy (MRS)	04-70540-07	Review; no change in position statement. Updated references.
34. Migalastat (Galafold)	09-J3000-12	Review and revision to guideline consisting of updating the position statement, precautions, related guidelines, and references. Added that migalastat will NOT be used in combination with pegunigalsidase (Elfabrio).
35. Mitapivat (Pyrukynd)	09-J4000-29	Review and revision to guideline; updated position statement and references.
36. Molecular Testing for the Management of Pancreatic Cysts, Barrett Esophagus, and Solid Pancreatic Lesions	05-86000-27	Position statements maintained; references updated.
37. Onasemnogene abeparvovec (Zolgensma)	09-J3000-30	Revision of guideline; Updated position statement.
38. Oxybate Oral Solutions (Sodium Oxybate, Xyrem, and Xywav) and Suspension (Lumryz)	09-J1000-06	Review and revision to guideline consisting of updating the description, position statement, and references. Added Sodium Oxybate oral solution by Amneal Pharmaceuticals, the second approved authorized generic of Xyrem, as a non-preferred and excluded product.
39. Pegcetacloplan (Empaveli) Infusion	09-J4000-04	Revision to update to vaccination requirement and agents not to be used in combination in the position statement. Update to contraindications and administration.
40. Pegunigalsidase (Elfabrio) IV	09-J4000-56	Review and revision of guidelines consisting of updates to the references.
41. Percutaneous Electrical Nerve Stimulation (PENS)	02-61000-03	Scheduled review. Revised description and position statement (added coverage criteria for IB-Stim®). Updated references.

42. Platelet-Derived Growth Factors and Platelet-Rich Plasma	02-10000-09	Position statements maintained; program exception and references updated.
43. Ravulizumab (Ultomiris) IV	09-J3000-26	Review and revision to guideline; consisting of updating the the position statement to include neuromyelitis optica spectrum disorder. The position statement also includes updating lab documentation requirements and agents not to be used in combination. Updates to coding and references.
44. Rozanolixizumab-noli (Rystiggo) Injection	09-J4000-55	Revision to guideline including updating lab documentation requirements and agents not to be used in combination in the position statement.
45. Satralizumab (Enspryng)	09-J3000-79	Review and revision to guideline; consisting of updating the position statement to remove requirement for alternative immunosuppressant therapy.
46. Secukinumab (Cosentyx) Injection and Infusion	09-J2000-30	Revision to guideline consisting of updating the position statement. Added a step requirement through a TNF inhibitor for all indications for initiation of IV Cosentyx.
47. Setmelanotide (Imcivree) Injection	09-J3000-90	Review and revision to guideline consisting of updating the precautions and references. New contraindication regarding a prior serious hypersensitivity reaction was added to the FDA-approved labeling.
48. Signal Averaged Electrocardiography (SAECG)	01-93000-22	Review: Position statement maintained; description and references updated.
49. Sodium phenylbutyrate-taurursodiol (Relyvrio) for oral suspension	09-J4000-42	Review and revision to guideline consisting of revising the position statement for sodium phenylbutyrate-taurursodiol (Relyvrio) therapy to not be medically necessary and updating references.
50. Sparsentan (Filspari)	09-J4000-48	Review and revision of guideline; updated references.

51. Surgical Treatments for Lymphedema and Lipedema	02-12000-18	Review; added position statement for reverse lymphatic mapping. Updated references.
52. Tezacaftor-Ivacaftor (Symdeko)	09-J2000-97	Review and revision to guideline; consisting of updating references.
53. Total Ankle Replacement	02-99221-15	Review: Position statements maintained; description and references updated.
54. Transcatheter Aortic Valve Replacement	02-33000-32	Review/revision. Deleted left ventricular ejection fraction greater than 20% criteria. Added statement for consideration of individuals who may be at increased surgical risk for open heart surgery. Updated references.
55. Transcatheter Pulmonary Valve Implantation	02-33000-33	Position statements maintained. Revised program exception.
56. Transmyocardial Revascularization (TMR)	02-33000-19	Review: Position statements maintained; description and references updated.
57. Upadacitinib (Rinvoq) Tablets	09-J3000-51	Revision to guideline consisting of updating the description section, position statement, and references. Removal of the step requirement of a systemic immunosuppressant for AD (based on new AD guidelines).
58. Voretigene Neparvovec-rzyl (Luxturna) Injection	09-J2000-96	Revision to guideline consisting of revising the position statement to limit genetic testing results to laboratory documentation and updating references.
59. Voxelotor (Oxbryta)	09-J3000-57	Review and revision to guidelines; updated position statement and references.
60. Vutrisiran (Amvuttra)	09-J4000-32	Review and revision to guideline; updated position statement and references.
61. Zilucoplan (Zilbrysq) Subcutaneous Injection	09-J4000-78	Revision to guideline consisting of updating the lab documentation 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

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

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.