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: 5/15/2025

New and Revised MCGs:	MCG Number	Update
1. Agalsidase Beta (Fabrazyme®) IV	09-J2000-59	Review and revision of guidelines consisting of updates to the precautions and references.
2. Allogeneic Pancreas Transplant	02-40000-17	Scheduled review. Maintained position statement and updated references.
3. Alpelisib (Vijoice)	09-J4000-28	Review and revision to guidline; consisting of updating references.
4. Amifampridine (Firdapse®)	09-J3000-22	Review and revision to guideline; consisting of updating the position statement to include increase the maximum dosing for Firdapse.
5. Anifrolumab-fnia (Saphnelo)	09-J4000-07	Revision to guideline consisting of updating position statement
6. Atidarsagene autotemcel (Lenmeldy) suspension for IV infusion	09-J4000-84	Review and revision to guideline consisting of revising the position statement for the ARSA enzyme activity to be below the normal range, remove the requirements for a matched donor and the labs for WBC, platelets, hepatic and renal function, and updating references.

7. **Auditory and Sensory Integration Therapy**	01-92502-13	Review; no change in position statement. Updated references.
8. **Bio-Engineered Skin and Soft Tissue Substitutes; Amniotic Membrane and Amniotic Fluid**	02-10000-11	Review: Human amniotic membrane coverage statement updated; investigational product list, coding, and references updated.
9. **Blepharoplasty/Brow Surgical Procedures**	02-65000-11	Scheduled review. Revised visual field criteria for blepharoplasty and blepharoptosis repair. Updated references.
10. **Cenegermin-bkbj (Oxervate®) Ophthalmic Solution**	09-J3000-15	Review and revision to guideline consisting of revising the position statement to allow additional corneal sensitivity tests and updating references.
11. **Certolizumab Pegol (Cimzia®) Injection**	09-J0000-77	Revision. Tremfya added among the preferred agents for CD for self-administered Cimzia.
12. **Durable Medical Equipment (DME)**	09-E0000-01	Review: Transfer system description and guideline updated in DME table.
13. **Elivaldogene autotemcel (Skysona) Suspension for Intravenous Infusion**	09-J4000-33	Review and revision to guideline consisting of revising the box warning to include acute myeloid leukemia,increasing the frequency of CBC monitoring to 3 months from 6 months, and updating the references.
14. **Evinacumab-dgnb (Evkeeza®) IV Infusion**	09-J3000-99	Review and revision to guideline consisting of updating the position statement and references.
15. **Excimer Laser Therapy for Treatment of Dermatologic Conditions**	02-10000-13	Review: Position statements maintained and references updated.
16. **Guselkumab (Tremfya®) Injection and Infusion**	09-J2000-87	Revision to guideline consisting of updating the description, position

		statement, dosage/administration, precautions, billing/coding, and references based on the new FDA-approved indication for CD in adults.
17. **Heart Transplant**	02-33000-23	Scheduled review. Maintained position statement and updated references.
18. **Image-Guided Radiation Therapy**	04-77260-19	Review; no change in position statement.
19. **Implantable Cardioverter Defibrillators and Cardiac Contractility Modulation (CCM) Therapy**	02-33000-34	Review: ICD replacement statement added; pediatric position statement, description, coding, and references updated.
20. **Infliximab Products [infliximab (Remicade®), Infliximab, infliximab-dyyb (Inflectra®), infliximab-abda (Renflexis®), and infliximab-axxq (Avsola®) intravenous infusions; and infliximab-dyyb (Zymfentra®) subcutaneous injection]**	09-J0000-39	Revision. Tremfya added among the preferred agents for CD for Zymfentra SC.
21. **Intensity-Modulated Radiation Therapy (IMRT)**	04-77260-22	Review; no change in position statement. Updated references.
22. **Iptacopan (Fabhalta®) Capsules**	09-J4000-80	Review and revision to guideline; updated position statement to include complement 3 glomerulopathy (C3G).
23. **Islet Transplantation**	02-40000-21	Scheduled review. Deleted coverage statement for allogeneic islet transplant and deleted code S2102. Added related MCG for Lantidra (09-J4000-58). Updated references.
24. **Knee Arthroplasty**	02-20000-60	Scheduled review. Revised description, maintained position statement and updated references.
25. **Laser Vitreolysis**	02-65000-14	Scheduled review. Revised description, maintained position statement and updated references.

26. **Leniolisib Phosphate (Joenja®)**	09-J4000-51	Review and revision to guidelines consisting of updates to the references.
27. **Lonafarnib (Zokinvy™)**	09-J3000-89	Review and revision to guideline; updated references.
28. **Magnetic Resonance Imaging (MRI) Abdomen and Pelvis**	04-70540-14	Review; no change in position statement.
29. **Magnetic Resonance Imaging (MRI) Brain and Head**	04-70540-11	Review; no change in position statement.
30. **Magnetic Resonance Imaging (MRI) Lower Extremity**	04-70540-16	Review; no change in position statement.
31. **Magnetic Resonance Imaging (MRI) Spine (Cervical, Thoracic, Lumbar)**	04-70540-17	Review; no change in position statement.
32. **Magnetic Resonance Imaging (MRI) Upper Extremity**	04-70540-15	Review; no change in position statement.
33. **Magnetic Resonance Spectroscopy (MRS)**	04-70540-07	Review; no change in position statement. Updated references.
34. **Migalastat (Galafold®) Capsule**	09-J3000-12	Review and revision of guidelines consisting of updates to the position statement and references. The Galafold (migalastat) Amenability Table search tool has a new web address.
35. **Mirikizumab-mrkz (Omvoh®) Injection and Infusion**	09-J4000-71	Revision. Tremfya added among the preferred agents for CD.
36. **Mitapivat (Pyrukynd)**	09-J4000-29	Review and revision to guideline; updated position statement and references
37. **Negative Pressure Wound Therapy (NPWT)**	09-E0000-37	Review: Position statements maintained; references updated.
38. **Neuromuscular Electrical Stimulation (NMES)**	09-E0000-25	Review: Position statement added for NMES used as a technique to increase blood circulation, reduce edema, or treat venous thrombosis; coding and references updated.

39. **New-To-Market Program for Medical Benefit Medications**	09-J4000-30	Addition of Tepylute (thiotepa) injection for intravenous use to the drug list.
40. **Ondansetron HCl (Zofran®) Injection**	09-J0000-98	Retire MCG.
41. **Oxybate Oral Solutions (Sodium Oxybate, Xyrem®, and Xywav®) and Suspension (Lumryz®)**	09-J1000-06	Revision to guideline consisting of updating the position statement. For type 2 narcolepsy, updated the prerequisites to a single step though either modafinil (Provigil) OR armodafinil (Nuvigil). Added "in consultation with" to specialist requirement. Increased the initial approval duration from 3 months to 12 months.
42. **Palivizumab (Synagis®)**	09-J0000-28	Review and revision to guideline; consisting of updating position statement and references.
43. **Pegunigalsidase (Elfabrio®) IV Infusion**	09-J4000-56	Review and revision of guidelines consisting of updates to the references.
44. **Pitolisant (Wakix)**	09-J3000-52	Review and revision to guideline; updated position statement and references.
45. **Preferred Agents and Drug List**	09-J9000-01	Revision. Tremfya added as a Step 1a agent for CD.
46. **Setmelanotide (Imcivree®) Injection**	09-J3000-90	Review and revision to guideline consisting of updating the description, position statement, dosage/administration, precautions/warnings, and references. The FDA-approved indications were expanded to include pediatric patients 2 years of age and older. New weight-based dosing for patients 2 to 6 years of age.
47. **Sparsentan (Filspari)**	09-J4000-48	Review and revision of guideline; updated references.

48. **Surgical Treatments for Lymphedema and Lipedema**	02-12000-18	Review; no change to position statements. Updated references.
49. **Tetrabenazine (Xenazine) and Deutetrabenazine (Austedo, Austedo XR)**	09-J1000-07	Review and revision to guideline; consisting of updating the references.
50. **Treatment of Autism Spectrum Disorders**	01-97000-08	Scheduled review. Maintained position statement and updated references.
51. **Valbenazine (Ingrezza, Ingrezza Sprinkle)**	09-J2000-81	Review and revision to guideline; consisting of updating the references.
52. **Voretigene Neparvovec-rzyl (Luxturna) Injection**	09-J2000-96	Review and revision to guideline consisting of updating the references.
53. **Vutrisiran (Amvuttra)**	09-J4000-32	Review and revision to guideline; updated position statement and 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
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.