Policy Review 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: 9/15/2025

New and Revised MCGs:	MCG Number	Update
1. **Apremilast (Otezla) Tablet**	09-J2000-19	Revision to guideline consisting of updating the description, position statement, dosage/administration, billing/coding, and references based the expanded FDA approved indication for the treatment of pediatric patients 6 years of age and older and weighing at least 20 kg with active PsA.
2. **Autologous Chondrocyte Implantation (ACI)**	02-20000-17	Scheduled review. Revised description, maintained position statement and updated references.
3. **Blood Glucose Monitors and Supplies**	09-E0000-14	Scheduled review. Maintained position statement and updated references.
4. **Brentuximab (Adcetris) Injection**	09-J1000-53	Review and revision to guideline; consisting of updating the position statement for Diffuse large B-cell lymphoma, High grade B-cell lymphoma, HIV-related B-cell lymphomas, PTLD, Mycosis Fungoides/Sezary syndrome, Classic Hodgkin Lymphoma, pediatric Hodgkin Lymphoma, and pediatric primary mediastinal lymphoma per NCCN.

5. **Bronchial Thermoplasty**	02-30000-12	Review; no change in position statement. Updated references.
6. **Carfilzomib (Kyprolis) Injection**	09-J1000-81	Revision to guidelines consisting of adding a new quadruple therapy regimen of carfilzomib, daratumumab, pomalidomide, and dexamethasone for patients with relapsed or refractory MM per NCCN guidelines.
7. **Chimeric Antigen Receptor (CAR) T-Cell Therapies**	09-J3000-94	Revision to guideline consisting of updating the description, position statement, dosage/administration, precautions, and references based on the removal of the REMS requirements from the package labeling of all CAR T-cell therapies. Revision to Carvykti criteria to allow use despite not being lenalidomide refractory when at least three prior lines of therapy for the member's MM have been tried.
8. **Computer Assisted Surgical Navigation**	02-99221-14	Review; no change in position statement. Updated references.
9. **Cryoablation of Liver Tumors**	02-40000-22	Scheduled review. Maintained position statement and updated references.
10. **Donislecel (Lantidra) Allogenic Islet Cell Transplant**	09-J4000-58	Review and revision to guidelines consisting of updating the references.
11. **Drugs and Biologics without Medical Coverage Guideline**	09-J0000-68	Revision to guideline; added Penpulimab-kcqx and Zusduri and removed Lumoxiti from Table 1.
12. **Edaravone (Radicava)**	09-J2000-82	Review and revision to guidelines consisting of updating the references.

13. **Elranatamab-bcmm (Elrexfio) Subcutaneous Injection**	09-J4000-64	Revision to guideline consisting of updating the description section, position statement, dosage/administration, and references, based on updated prescribing information that include an every 4-week dosing regimen for patients who have maintained a response following 24 weeks of treatment at the biweekly dosing schedule.
14. **Emapalumab-lzsg (Gamifant) IV**	09-J3000-24	Review and revision to guideline; consisting of updating the position statement to include HLH/MAS in Still's disease/sJIA and HLH-like syndrome following immune checkpoint inhibitor therapy.
15. **Epcoritamab-bysp (Epkinly) SQ Injection**	09-J4000-61	Review and revision to guideline consisting of revising the position statemen to include the NCCN 2A recommendations of combination therapy with gemcitabine and oxaliplatin as second-line or subsequent therapy for HIV-related B-cell lymphomas, diffuse large B-cell lymphoma, high-grade B-cell lymphoma, or monomorphic post-transplant lymphoproliferative disorder (B-cell type).
16. **External Infusion Pumps (non-insulin)**	09-E0000-10	Scheduled review. Maintained position statement and updated references.
17. **Extracorporeal Membrane Oxygenation (ECMO) for Adult Conditions**	02-33000-40	Scheduled review. Maintained position statement and updated references.
18. **Facet Arthroplasty**	02-20000-37	Scheduled review. Revised description, maintained position statement and updated references.
19. **Fecal Microbiota Transplantation**	02-40000-24	Scheduled review. Revised description, maintained position statement and updated references.

20. **Glofitamab-gxbm (Columvi) IV Infusion**	09-J4000-60	Review and revision to guideline consisting of revising the discussion section to reflect the NCCN recommendations and updating references.
21. **Home Prothrombin Time Monitoring**	01-99000-06	Scheduled review. Maintained position statement and updated references.
22. **Home Spirometry**	09-E0000-36	Review: Position statement maintained, and references updated.
23. **Investigational Services**	09-A0000-03	Code 97610 (UltraMIST Low-Freq Ultrasound Wound Therapy System) reviewed; code 0563T (TearCare System) reviewed; code 0716T (CADScor System) reviewed.
24. **Linvoseltamab-gcpt (Lynozyfic) IV Infusion**	09-J5000-27	New Medical Coverage Guideline.
25. **Lower Limb Microprocessor-Controlled Prosthetics**	09-L0000-06	Review; no change in position statement. Added code L5827. Updated references.
26. **Magnetic Resonance - Guided High Intensity Focused Ultrasound Ablation**	02-56000-27	Review; no change to position statement.
27. **Medical & Surgical Management of Sleep Apnea, Snoring, and Other Conditions of the Soft Palate and Nasal Passages**	02-40000-16	Review: Position statements maintained and references updated.
28. **Outpatient Pulmonary Rehabilitation**	01-94010-07	Scheduled review. Maintained position statement and updated references.
29. **Pegcetacloplan (Empaveli) Infusion**	09-J4000-04	Review and revision to guideline; consisting of including C3 glomerulopathy and primary IC-MPGN into the position statement.
30. **Positive Airway Pressure Devices**	09-E0000-21	Review: Position statements maintained; references updated.

31. **Positron Emission Tomography (PET) Miscellaneous Applications**	04-78000-18	Review; no change in position statement. Updated references.
32. **Reduction Mammaplasty**	02-12000-11	Review; no change to position statement. Updated references.
33. **Riluzole (Tiglutik, Exservan)**	09-J3000-38	Review and revision to guidelines consisting of updating the references.
34. **Rozanolixizumab-noli (Rystiggo) Injection**	09-J4000-55	Revision to guideline including updating continuation requirements in the position statement.
35. **Selective Internal Radiation Therapy**	04-77260-21	Review; no change to position statement. Updated references.
36. **Sleep Testing**	01-95828-01	Review: "Acute" removed from comorbid medical conditions criteria; all other statements maintained and references updated.
37. **Sodium phenylbutyrate-taurursodiol (Relyvrio) for oral suspension**	09-J4000-42	Retire the guideline since the manufacturer voluntarily withdrew sodium phenylbutyrate-taurursodiol (Relyvrio) from the market in April 2024.
38. **Step Therapy Requirements for Medicare Outpatient (Part B) Medications**	09-J3000-39	Review and revision to guidelines, consisting of update to existing ST categories: non-preferred drug Avtozma [Autoimmune Therapy], non-preferred Jubbonti, Stoboclo, Conexxence, Prolia [Bone Remodeling Agents], non-preferred Wyost, Osenvelt, Bomyntra , Xgeva [Cancer and Supportive Therapy], non-preferred Opuviz, Yesafili [Ophthalmic Agents].
39. **Technologies for the Evaluation of Malignant Melanoma**	01-96900-03	Review: Position statement maintained; references updated.
40. **Telisotuzumab Vedotin (Emrelis) IV infusion**	09-J5000-24	New Medical Coverage Guideline.

41. **Tofersen (Qalsody) Intrathecal Injection**	09-J4000-59	Review and revision to guideline consisting of updating references.
42. **Tolvaptan (Jynarque) Tablet**	09-J3000-09	Revision to guideline requiring intolerance or hypersensitivity to the brand name product (i.e., Jynarque) for generic product requests.
43. **Transtympanic Micropressure Applications as a Treatment of Meniere's Disease**	09-E0000-46	Review: Position statement maintained and references updated.
44. **Treatment of Hyperhidrosis**	01-94010-08	Scheduled review. Maintained position statement and updated references.
45. **Tumor Treating Fields Therapy**	02-61000-10	Revision. Updated references for the use of TTFT treatment for non-small cell lung cancer. Maintained position statement.
46. **Vascular Endothelial Growth Factor Inhibitors for Ocular Neovascularization**	09-J1000-78	Revision to the guideline consisting of not requiring a bevacizumab (Avastin) or bevacizumab biosimilar step for Lucentis, Byooviz, and Cimerli for Susvimo rescue.

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

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.