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: 9/15/2026

New and Revised MCGs:	MCG Number	Update
1. Amivantamab-vmjw (Rybrevant™), Amivantamab/Hyaluronidase-lpuj (Rybrevant Faspro™)	09-J4000-02	Revision to guideline; updated Position Statement and Dosing/Administration.
2. Autologous Chondrocyte Implantation (ACI)	02-20000-17	Review; no change in position statement. Updated references.
3. Autologous Hematopoietic Cell Transplantation	02-38241-01	Revision: Position statements and references updated.
4. Bronchial Thermoplasty	02-30000-12	Review; no change in position statement. Updated references.
5. Computer Assisted Surgical Navigation	02-99221-14	Review; no change in position statement.
6. Corticosteroid Intravitreal Implant and Injection	09-J2000-35	Revision to the guideline consisting of adding triamcinolone acetonide ocular suspension injection (Triesence) to the position statement for the treatment of ocular indications but not requiring prior authorization, revising the MCG title and respective sections with triamcinolone acetonide ocular suspension injection (Triesence) prescribing information and billing/coding, and updating references.
7. Danicopan (Voydeya™) Tablets	09-J4000-88	Review and revision to guideline; consisting of updating continuation language if approved by another health plan.
8. Donislecel (Lantidra) allogeneic islet cell transplant	09-J4000-58	Review and revision to guidelines consisting of updating the references.

9.	Drug Waste Reduction	09-J5000-54	Revision: Loargys added to the list of in-scope medications.
10.	Drugs and Biologics without a Medical Coverage Guideline (Orphan Drugs and Off-Label and Labeled Use of FDA Approved Drugs)	09-J0000-68	Revision to guideline; added Decnupaz to table 1 and Lexicomp to table 2.
11.	Eculizumab Products [eculizumab (Soliris®), eculizumab-aagh(Epysqli), eculizumab-aeeb (Bkemv)] Injection	09-J1000-17	Review and revision to guideline; consisting of updating preferred agents for Myasthenia Gravis and updated continuation criteria if paid by another health plan.
12.	Epcoritamab-bysp (Epkinly) SQ Injection	09-J4000-61	Review and revision to the guideline consisting of revising the Dosing/Administration section to assess the patient when determining if the first 48 mg dose for LBCL should be given in the hospital or outpatient setting and updating references.
13.	Exagamglogene autotemcel (Casgevy) suspension for IV infusion	09-J4000-82	Revision of the guideline consisting of revising the background, position statement, and dosing/administration to include the new FDA approved age of 2 years and older and updating references.
14.	Extracorporeal Membrane Oxygenation (ECMO) for Adult Conditions	02-33000-40	Annual review: Position statements maintained and references updated.
15.	Facet Arthroplasty	02-20000-37	Annual review: Position statement, description, and references updated.
16.	Familial Chylomicronemia Syndrome and Severe Hypertriglyceridemia	09-J5000-39	Revision to the guideline position statement to allow prescribing in consultation with a specialist for olezarsen (Tryngolza) and plozasiran (Redemplo) therapy and updating the MCG title, background, position statement, dosing/administration, warnings/precautions, and billing to reflect the new FDA approved indication for olezarsen (Tryngolza) for the treatment of severe hypertriglyceridemia.
17.	Fam-trastuzumab deruxtecan-nxki injection (Enhertu®)	09-J3000-58	Revision: Added NCCN indications to the Position Statement.
18.	Fecal Microbiota Transplantation	02-40000-24	Review; no change in position statement. Updated references.

19. **Fosdenopterin Hydrobromide (Nulibry)**	09-J3000-95	Review and revision to guideline; updated position statement and references.
20. **Glofitamab-gxbm (Columvi) IV Infusion**	09-J4000-60	Admin: clarification of glofitamab-gxbm (Columvi) dosing.
21. **Home Spirometry**	09-E0000-36	Annual review: Position statement maintained; references updated.
22. **Isatuximab-irfc Intravenous Infusion (Sarclisa) and Subcutaneous Injection (Sarclisa Escena)**	09-J3000-67	Revision to guideline consisting of updating the description, position statement, dosage/administration, precautions, billing/coding information, and references, based on the inclusion of subcutaneous Sarclisa Escena.
23. **Lower Limb Microprocessor-Controlled Prosthetics**	09-L0000-06	Review; no change in position statement. Updated references.
24. **Magnetic Resonance-Guided High Intensity Focused Ultrasound Ablation**	02-56000-27	Review; no change to position statement. Updated references.
25. **Marnetegragene autotemcel (Kresladi) Suspension for IV infusion**	09-J5000-61	New Medical Coverage Guideline – Marnetegragene autotemcel (Kresladi) is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of genetically confirmed of leukocyte adhesion deficiency type 1 (LAD-1) who have a mutation in the ITGB2 gene with severe disease for whom hematopoietic stem cell transplantation is appropriate and no suitable human leukocyte antigen (HLA)-matched sibling stem cell donor is available.
26. **Medical & Surgical Management of Sleep Apnea, Snoring, and Other Conditions of the Soft Palate and Nasal Passages**	02-40000-16	Annual review: Hypoglossal nerve stimulation position statement and references updated.
27. **New-To-Market Program for Medical Benefit Medications**	09-J4000-30	Added Genglycos (pariglasgene brecaparvovec-opnr) to the drug list. Removed Kresladi (marnetegragene autotemcel) from the drug list.
28. **Niemann-Pick Disease Type C**	09-J5000-40	Revision to the guideline consisting of updating the position statement to require miglustat in combination with arimoclomol (Miplyffa) and to require a step through miglustat therapy, unless there is a documented intolerance, hypersensitivity, or contraindication to miglustat, before initiation of levacetylleucin (Aqneursa).

29. **Nipocalimab-aahu (Imaavy)**	09-J5000-25	Review and revision to guideline consisting of updating the position statement to remove a step requirement through preferred agents.
30. **Non-Covered Services**	09-A0000-00	Revision; Code A4633 removed (refer to policy 02-10000-30); coding table reformatted; DME codes removed (refer to policy 09-E0000-01).
31. **Oral and IV Amyotrophic Lateral Sclerosis**	09-J5000-41	Review and revision of the guideline to remove riluzole film (Exservan), which was discontinued by the manufacturer in July 2024, from the position statement and respective sections of the MCG and to update the references.
32. **Oral Therapy for Gaucher and Pompe Disease**	09-J0000-76	Revision to guideline; consisting of updating position statement, coding.
33. **Oscillatory Devices Used in the Home for the Treatment of Cystic Fibrosis and Other Respiratory Disorders**	09-E0000-28	Annual review: Multifunction airway clearance devices statement updated; references updated.
34. **Positron Emission Tomography (PET) Miscellaneous Applications**	04-78000-18	Review; no change in position statement. Updated references.
35. **Ravulizumab (Ultomiris™) Injection**	09-J3000-26	Review and revision to guideline; consisting of updating the position statement to remove the subcutaneous administration of ravulizumab and updating continuation criteria if approved by another healthplan.
36. **Resmetirom (Rezdiffra) tablets**	09-J4000-85	Revision to the guideline position statement regarding non-invasive liver tests for documenting Stage F2 to F3 fibrosis.
37. **Rituximab Products [rituximab (Rituxan®), rituximab-abbs(Truxima®), rituximab-arrx (Riabni™), rituximab-pvvr (Ruxience™), and rituximab;hyaluronidase (Rituxan Hycela™)**	09-J0000-59	Review and revision to guideline; consisting of updating dosing and including Lexicomp in the compendia table and added Table 9. NCCN updates include addition of Kaposi sarcoma-associated herpes virus and revisions to chronic GVHD, PTLD and immune-checkpoint inhibitor toxicities.
38. **Rozanolixizumab-noli (Rystiggo) Injection**	09-J4000-55	Update to criteria to include a step through preferred agents and revision of continuation criteria if approved by another healthplan.

39. Sacituzumab Govitecan-hziy (Trodelvy)	09-J3000-76	Revision: Updated Position Statement per NCCN.
40. Sleep Testing	01-95828-01	Annual review: Position statements maintained and references updated.
41. Technologies for the Evaluation of Malignant Melanoma	01-96900-03	Annual review: Position statement maintained; references updated.
42. Teplizumab (Tzield) Injection	09-J4000-40	Revision to guideline consisting of updating the description section, position statement, dosage/administration, precautions, billing/doing and references based on the expanded FDA-approved indication for recently diagnosed with Stage 3 T1D.
43. Teprotumumab (Tepezza®) Infusion	09-J3000-64	Revision to guideline consisting of updating the description and position statement. Added requirement that member has not been previously treated with veligrotug (Lumvoa).
44. Tofersen (Qalsody) for Intrathecal Injection	09-J4000-59	Review and revision to guideline consisting of updating references.
45. Treatment of Hyperhidrosis	01-94010-08	Annual review: Position statements maintained; references updated.
46. Ultraviolet Light Therapy System for Home Use	02-10000-30	New Medical Coverage Guideline.
47. Zilucoplan (Zilbrysq) Subcutaneous Injection	09-J4000-78	Review and revision to guideline consisting of updating the step requirements in the position statement and update to continuation criteria if approved by another healthplan.

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

Generic/Brand	MCG Number
Lenvatinib (Lenvima)	09-J2000-38
Lorlatinib (Lorbrena)	09-J3000-23
Midostaurin (Rydapt)	09-J2000-86

Alectinib (Alecensa)	09-J2000-56	Neratinib (Nerlynx)	09-J2000-83
Alpelisib (Piqray)	09-J3000-42	Niraparib (Zejula)	09-J2000-77
Apalutamide (Erleada)	09-J3000-03	Olaparib (Lynparza)	09-J2000-32
Avapritinib (Ayvakit)	09-J3000-63	Osimertinib (Tagrisso)	09-J2000-55
Axitinib (Inlyta)	09-J1000-67	Palbociclib (Ibrance)	09-J2000-34
Binimetinib (Mektovi)	09-J3000-20	Panobinostat (Farydak)	09-J2000-37
Brigatinib (Alunbrig)	09-J2000-84	Pazopanib (Votrient)	09-J1000-49
Ceritinib (Zykadia)	09-J2000-17	Pexidartinib (Turalio)	09-J3000-47
Cobimetinib (Cotellic)	09-J2000-53	Pomalidomide (Pomalyst)	09-J1000-95
Crizotinib (Xalkori)	09-J1000-57	Ponatinib (Iclusig)	09-J1000-89
Dabrafenib (Tafinlar)	09-J2000-00	Regorafenib (Stivarga)	09-J1000-83
Dacomitinib (Vizimpro)	09-J3000-18	Rucaparib (Rubraca)	09-J2000-72
Darolutamide (Nubeqa)	09-J3000-50	Ruxolitinib (Jakafi)	09-J1000-63
Dasatinib (Sprycel)	09-J1000-43	Selinexor (Xpovio)	09-J3000-44
Duvelisib (Copiktra)	09-J3000-14	Sonidegib (Odomzo)	09-J2000-45
Enasidenib (Idhifa)	09-J2000-90	Sorafenib (Nexavar)	09-J1000-50
Encorafenib (Braftovi)	09-J3000-19	Sunitinib Malate (Sutent)	09-J1000-51
Entrectinib (Rozlytrek)	09-J3000-48	Talazoparib (Talzenna)	09-J3000-21
Enzalutamide (Xtandi)	09-J1000-85	Topotecan HCl (Hycamtin)	09-J1000-02
Erdafitinib (Balversa)	09-J3000-31	Trametinib (Mekinist)	09-J1000-99
Gefitinib (Iressa)	09-J2000-44	Tretinoin Oral	09-J1000-61
Gilteritinib (Xospata)	09-J3000-28	Trifluridine-Tipiracil (Lonsurf)	09-J2000-46
Glasdegib (Daurismo)	09-J3000-27	Vandetanib (Caprelsa)	09-J1000-38
Idelalisib (Zydelig)	09-J2000-23	Vemurafenib (Zelboraf)	09-J1000-40
Ivosidenib (Tibsovo)	09-J3000-13	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 Guidelines (MCG) for these therapies 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

09-J5000-50, Transthyretin Amyloidosis (ATTR)

A complete list of previous MCGs that have been consolidated is shown below.

Generic/Brand	MCG Number
Acoramidis (Attruby)	09-J5000-11
Eplontersen (Wainua)	09-J4000-77
Patisiran Sodium (Onpattro)	09-J3000-16
Tafamidis (Vyndamax, Vyndaqel) Oral	09-J3000-41
Vutrisiran (Amvuttra)	09-J4000-32

09-J5000-52, Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Modulators

A complete list of previous MCGs that have been consolidated is shown below.

Generic/Brand	MCG Number
Ivacaftor (Kalydeco) Oral	09-J1000-68
Lumacaftor Ivacaftor (Orkambi) Capsule	09-J2000-29
Tezacaftor-Ivacaftor (Symdeko)	09-J2000-97
Elexacaftor-tezacaftor-ivacaftor (Trikafta)	09-J3000-53
Deutivacaftor-Tezacaftor- Vanzacaftor (Alyftrek)	09-J5000-10

09-J5000-53, Deflazacort (Emflaza), Vamorolone (Agamree)

A complete list of previous MCGs that have been consolidated is shown below.

Generic/Brand	MCG Number
Deflazacort (Emflaza)	09-J2000-76
Vamorolone (Agamree)	09-J4000-76

09-J5000-43, Huntington's Chorea and Tardive Dyskinesia Agents

A complete list of previous MCGs that have been consolidated is shown below.

Generic/Brand	MCG Number

Tetrabenazine (Xenazine) and Deutetrabenazine (Austedo, Austedo XR)	09-J1000-07
Valbenazine (Ingrezza, Ingrezza Sprinkle)	09-J2000-81

09-J5000-35, Interleukin-5 (IL-5) Inhibitors

A complete list of previous MCGs that have been consolidated is shown below.

Generic/Brand	MCG Number
Benralizumab (Fasenra)	09-J2000-92
Mepolizumab (Nucala)	09-J2000-54
Reslizumab (Cinqair) IV infusion	09-J2000-63

09-J5000-37, IL-13 Antagonists

A complete list of previous MCGs that have been consolidated is shown below.

Generic/Brand	MCG Number
Lebrikizumab-lbkz (Ebglyss)	09-J5000-00
Tralokinumab-ldrm (Adbry) Injection	09-J4000-20

09-J5000-51, Lupus

A complete list of previous MCGs that have been consolidated is shown below.

Generic/Brand	MCG Number
Anifrolumab-fnia (Saphnelo)	09-J4000-07
Belimumab (Benlysta) Injection	09-J1000-35
Voclosporin (Lupkynis)	09-J3000-96

09-J5000-44, Multiple Sclerosis: Oral and Self Injectable Therapy

A complete list of previous MCGs that have been consolidated is shown below.

Generic/Brand	MCG Number
Brand Aubagio Tablets	09-J1000-82
Brand Gilenya and Tascenso ODT	09-J1000-30
Brand Tecfidera, Diroximel fumarate (Vumerity), Monomethyl fumarate (Bafiertam) Capsule	09-J1000-96
Cladribine (Mavenclad) tablets	09-J3000-34
Multiple Sclerosis Self Injectable Therapy (Interferon beta products and Copaxone)	09-J1000-39
Ofatumumab (Kesimpta)	09-J3000-84
Ponesimod (Ponvory) Tablet	09-J3000-98
Siponimod (Mayzent) tablets	09-J3000-35

09-J5000-40, Niemann-Pick Disease Type C

A complete list of previous MCGs that have been consolidated is shown below.

Generic/Brand	MCG Number
Arimoclomol (Miplyffa) Capsules	09-J5000-04
Levacetylleucin (Aqneursa) Oral Suspension	09-J5000-05

09-J3000-65, Oncology Self-administered Medications

A complete list of previous MCGs that have been consolidated is shown below.

Generic/Brand	MCG Number
Abiraterone Acetate (Yonsa, Zytiga) Tablets	09-J1000-36
Bosutinib (Bosulif) Capsules and Tablets	09-J1000-84
Ibrutinib (Imbruvica)	09-J2000-09
Imatinib (Imkeldi) Oral Solution	09-J5000-15
Ixazomib (Ninlaro) Capsule	09-J2000-51
Momelotinib (Ojjaara) Tablets	09-J4000-69
Nilotinib Capsules (Nilceya and Tasigna) and Tablets (Danziten)	09-J1000-48
Pacritinib (Vonjo) Capsule	09-J4000-24
Ropeginterferon alfa-2b-njft (Besremi)	09-J4000-19

09-J5000-41, Oral and IV Amyotrophic Lateral Sclerosis

A complete list of previous MCGs that have been consolidated is shown below.

Generic/Brand	MCG Number
Edaravone (Radicava)	09-J5000-04
Riluzole (Exservan, Tiglutik)	09-J3000-38

09-J5000-45, Osteoporosis Self-Injectable Therapy

A complete list of previous MCGs that have been consolidated is shown below.

Generic/Brand	MCG Number
Abaloparatide (Tymlos)	09-J2000-85
Teriparatide (Forteo, Bonsity, Teriparatide) injection	09-J0000-47

09-J5000-49, Phenylketonuria (PKU)

A complete list of previous MCGs that have been consolidated is shown below.

Generic/Brand	MCG Number
Pegvaliase-pqpz (Palynziq)	09-J3000-07
Sapropterin (Kuvan) Tablets	09-J0000-74

09-J5000-46, Thrombocytopenia Oral Therapy

A complete list of previous MCGs that have been consolidated is shown below.

Generic/Brand	MCG Number
Avatrombopag (Doptelet, Doptelet Sprinkle)	09-J3000-02
Eltrombopag (Promacta, Alvaiz)	09-J1000-13
Fostamatinib (Tavalisse)	09-J3000-00
Lusutrombopag (Mulpleta) Tablet	09-J3000-11
Rilzabrutinib (Wayrilz)	09-J5000-30

09-J5000-47, Urea Cycle Disorders

A complete list of previous MCGs that have been consolidated is shown below.

Generic/Brand	MCG Number
Glycerol Phenylbutyrate (Ravicti)	09-J1000-98
Sodium Phenylbutyrate (Buphenyl, Olpruva, Pheburane)	09-J1000-97

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.