

[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: 5/15/2026

| 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 references. |
| 2. Alpelisib (Vijoice) | 09-J4000-28 | Review and revision to guideline; consisting of updating references. |
| 3. Atidarsagene autotemcel (Lenmeldy) suspension for IV infusion | 09-J4000-84 | Review and revision to guideline consisting of updating references. |
| 4. Auditory and Sensory Integration Therapy | 01-92502-13 | Review; no change in position statement. |
| 5. Bio-Engineered Skin and Soft Tissue Substitutes; Amniotic Membrane and Amniotic Fluid | 02-10000-11 | Annual review: Investigational products list, reimbursement section, and references updated. |
| 6. Cenegermin-bkbj (Oxervate®) Ophthalmic Solution | 09-J3000-15 | Review and revision to guideline consisting of updating the references. |
| 7. Clotting Factors and Coagulant Blood Products | 09-J0000-34 | Revision to guideline; updated position statement. |
| 8. Crizanlizumab-tcma (Adakveo) | 09-J3000-56 | Review and revision of guideline; Updated position statement and references. |
| 9. Diazoxide Choline (Vykat XR) Tablet | 09-J5000-21 | Review and revision to guidelines consisting of update to the references. |
| 10. Durable Medical Equipment (DME) | 09-E0000-01 | Review: DME table updated.. |
| 11. Efgartigimod alfa-fcab (Vyvgart, Vyvgart Hytrulo) injection | 09-J4000-18 | Update to position statement and dosing for labeling changes of Vyvgart Hytrulo. |

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| 12. <u>Elivaldogene autotemcel (Skysona) Suspension for Intravenous Infusion</u> | 09-J4000-33 | Review and revision to guideline consisting of revising the box warning to reflect the hematologic malignancies from Skysona treatment and the FDA-approved indication for patients without an available HLA-matched donor and updating the references. |
| 13. <u>Evinacumab-dqnb (Evkeeza®) IV Infusion</u> | 09-J3000-99 | Review and revision to guideline consisting of updating the position statement, dosage/administration, and references. Age for eligibility expanded to 1 year of age or older. Updated diagnostic criteria for HoFH. |
| 14. <u>Excimer Laser Therapy for Treatment of Dermatologic Conditions</u> | 02-10000-13 | Annual review: Position statements maintained; references updated. |
| 15. <u>Familial Chylomicronemia Syndrome</u> | 09-J5000-39 | New Medical Coverage Guideline: Adding the newly FDA approved plozasiran (Redemplo) SQ injection to the 09-J5000-07, olezarsen sodium (Tryngolza) SQ injection criteria to create the Familial Chylomicronemia Syndrome criteria and requiring a step through olezarsen (Tryngolza) for plozasiran (Redemplo) therapy and not allowing use of olezarsen (Tryngolza) and plozasiran (Redemplo) in combination. |
| 16. <u>Guselkumab (Tremfya®) Injection and Infusion</u> | 09-J2000-87 | Revision to guideline consisting of clarifying the approval duration and start date for Tremfya subcutaneous injection following Tremfya IV induction. |
| 17. <u>Image-Guided Radiation Therapy</u> | 04-77260-19 | Review; no change in position statement. |
| 18. <u>Immune Globulin Therapy</u> | 09-J0000-06 | Revision to guideline; including addition of Gammagard Liquid ERC as a non-preferred agent. |
| 19. <u>Implantable Cardioverter Defibrillators and Cardiac Contractility Modulation (CCM) Therapy</u> | 02-33000-34 | Annual review: Position statements maintained; references updated. |
| 20. <u>In Vitro Chemoresistance and Chemosensitivity Assays</u> | 05-86000-11 | Annual review: Position statements maintained; references updated. |
| 21. <u>Infliximab Products [Infliximab (Remicade®), Infliximab, infliximab-dyyb (Inflectra®), infliximab-abda (Renflexis®), and infliximab-axxq (Avsola®) intravenous</u> | 09-J0000-39 | Revision to guideline consisting of clarifying the approval duration and start date for Zymfentra subcutaneous injection following IV treatment with an infliximab product. |

infusions; and infliximab-dyyb (Zymfentra®) subcutaneous injection]

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| 22. Intensity-Modulated Radiation Therapy (IMRT) | 04-77260-22 | Review; no change in position statement. Updated references. |
| 23. Investigational Services | 09-A0000-03 | Code 0563T (TearCare System) reviewed. |
| 24. Knee Arthroplasty | 02-20000-60 | Review; no change in position statement. |
| 25. Leniolisib Phosphate (Joenja®) | 09-J4000-51 | Review and revision to guidelines consisting of updates to the precautions and references. |
| 26. Lonafarnib (Zokinvy™) | 09-J3000-89 | Review and revision to guideline; updated references. |
| 27. Magnetic Resonance Imaging (MRI) Abdomen and Pelvis | 04-70540-14 | Review; pelvic MRI: added statement for Peyronie's disease; revised prostate MRI. Updated references. |
| 28. Magnetic Resonance Imaging (MRI) Brain and Head | 04-70540-11 | Review; no change in position statement. |
| 29. Magnetic Resonance Imaging (MRI) Lower Extremity | 04-70540-16 | Review; no change in position statement. |
| 30. Magnetic Resonance Imaging (MRI) Spine (Cervical, Thoracic, Lumbar) | 04-70540-17 | Review; no change in position statement. |
| 31. Magnetic Resonance Imaging (MRI) Upper Extremity | 04-70540-15 | Review; no change in position statement. |
| 32. Magnetic Resonance Spectroscopy (MRS) | 04-70540-07 | Review; no change in position statement. Updated references. |
| 33. Migalastat (Galafold®) Capsule | 09-J3000-12 | Review and revision of guidelines consisting of updates to the references. |
| 34. Mirikizumab-mrkz (Omvoh®) Injection and Infusion | 09-J4000-71 | Revision to guideline consisting of clarifying the approval duration and start date for Omvoh subcutaneous injection following Omvoh IV induction. |
| 35. Mitapivat (Pyrukynd) | 09-J4000-29 | Review and revision to guideline; updated coding and references. |
| 36. 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, dosage/administration, |

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| | | precautions, and references. True generics of sodium oxybate are now available. |
| 37. Pegunigalsidase (Elfabrio®) IV Infusion | 09-J4000-56 | Review and revision of guidelines consisting of updates to the position statement, drug availability, precautions, and references. |
| 38. Pitolisant (Wakix) | 09-J3000-52 | Review and revision to guideline; updated position statement, dosage/administration, coding, and references. |
| 39. Prademagene zamikeracel (Zevaskyn) gene-modified cellular sheet | 09-J5000-26 | New Medical Coverage Guideline. |
| 40. Risankizumab-rzaa (Skyrizi®) Injection and Infusion | 09-J3000-45 | Revision to guideline consisting of clarifying the approval duration and start date for Skyrizi subcutaneous injection following Skyrizi IV induction. |
| 41. Setmelanotide (Imcivree®) Injection | 09-J3000-90 | Review and revision to guideline consisting of updating the description, position statement, dosage/administration, precautions and references. New FDA-approved indication for acquired hypothalamic obesity. |
| 42. 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 Exdensur [Asthma Therapy] non-preferred Orencia [Autoimmune Therapy], Axtle, Pemfexy, Pemrydi RTU, Avegmsi, Boruzu, Kyxata, Docivyx, Beizray, Tepylute, Kyprolis [Cancer and Supportive Therapy]. Addition of new ST categories for non-preferred Krystexxa [Gout Agents] and non-preferred Qfitlia, Hympavzi, Alhemo, Altuviio, Hemlibra [Hemophilia A Agents]. |
| 43. Surgical Treatments for Lymphedema and Lipedema | 02-12000-18 | Review; no change in position statement. |
| 44. Tenapanor (Xphozah) Tablet | 09-J5000-13 | Review and revision to guidelines consisting of updates to the references. |
| 45. Ustekinumab Products (Stelara® and biosimilars) | 09-J1000-16 | Revision to guideline consisting of clarifying the approval duration and start date for subcutaneous injection of a ustekinumab product following IV induction with a ustekinumab product. |
| 46. Vedolizumab (Entyvio®) Injection and Infusion | 09-J2000-18 | Revision to guideline consisting of clarifying the approval duration and start date for |

Entyvio subcutaneous injection following Entyvio IV treatment.

47. [Voretigene Neparvec-rzyl \(Luxturna\) Injection](#)

09-J2000-96

Review and revision to guideline consisting of updating the gene therapy definition 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 | Generic/Brand | MCG Number |
|---------------------------|-------------|----------------------------------|-------------|
| Abemaciclib (Verzenio) | 09-J2000-93 | Lenvatinib (Lenvima) | 09-J2000-38 |
| Acalabrutinib (Calquence) | 09-J2000-94 | Lorlatinib (Lorbrena) | 09-J3000-23 |
| Afatinib (Gilotrif) | 09-J2000-06 | 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 (Palyntiq) | 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 (Wayriz) | 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.