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: 11/15/2024

New and Revised MCGs:	MCG Number	Update
1. Adalimumab Products (Humira and biosimilars)	09-J0000-46	Revision to guideline consisting of updating the position statement and other section. Tremfya added as Step 1a agent for UC.
2. Adjunctive Techniques for Screening, Surveillance, and Risk Classification of Barrett Esophagus and Esophageal Dysplasia	05-87000-01	Review: Updates to position statement, billing and coding information and program exceptions.
3. Afamitresgene Autoleucel (Tecelra)	09-J4000-96	New Medical Coverage Guideline.
4. Apremilast (Otezla) Tablet	09-J2000-19	Revision to guideline consisting of updating the description, position statement, billing/coding, other section, and references based the new FDA approved indication for the treatment of pediatric patients 6 years of age and older and weighing at least 20 kg with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. A new 60-count bottle of 20 mg tablets was released to support the 20 mg BID maintenance dosing in patients 20 to 50 kg.

5. **Axatilimab (Niktimvo)**	09-J4000-98	New Medical Coverage Guideline.
6. **Balloon Dilation of the Eustachian Tube**	02-31000-02	Review: Position statements maintained; description and references updated.
7. **Belumosudil (Rezurock) Tablets**	09-J4000-08	Review and revision to guideline; consisting of updating the continuation criteria, dosing and references.
8. **Bimekizumab-bkzx (Bimzelx) Injection**	09-J4000-70	Revision to guideline consisting of updating the description section, position statement, dosage/administration, billing/coding, related guidelines, other section, and references based on the new FDA-approved indications for AS, nr-axSpA, PsA. Bimzelx is a step 3c agent for these uses.
9. **Bone Mineral Density Studies**	04-70000-21	Review; no change to position statement. Updated references.
10. **Certolizumab Pegol (Cimzia) Injection**	09-J0000-77	
11. **Computed Tomography Angiography (CTA) Chest (non coronary)**	04-70450-07	Review; no change to position statement. Updated references.
12. **Denileukin diftitox-cxdl (Lymphir) injection**	09-J4000-97	New Medical Coverage Guideline.
13. **Drugs and Biologics without Medical Coverage Guideline**	09-J0000-68	Revision to guideline; added Tecentriq Hybreza to table 1.
14. **External Insulin Infusion Pumps and Continuous Glucose Monitors**	01-99000-03	Revision. Updated Position Statement regarding the use of software and remote, mobile and wireless communication, for clarity.
15. **Genetic Testing for Hereditary Breast Ovarian Cancer Syndrome and Other High-Risk Cancers (BRCA1, BRCA2, PALB2)**	05-82000-30	Review: Position statements, description, and references updated.

16. **Genetic Testing for Lynch Syndrome and Other Inherited Colon Cancer Syndromes**	05-82000-31	Review: Position statements maintained; description and references updated.
17. **Guselkumab (Tremfya) Injection**	09-J2000-87	Revision to guideline consisting of updating the description, position statement, dosage/administration, precautions, billing/coding, related guidelines, other section, and references based on the new FDA-approved indication for UC in adults. Position statement divided into one section for "SUBCUTANEOUS TREMFYA (PHARMACY BENEFIT)" and one section for "INTRAVENOUS TREMFYA (MEDICAL BENEFIT)".
18. **H.P. Acthar® Gel, Purified Cortrophin® Gel (Repository corticotropin)**	09-J1000-15	Revision to guideline; updated dosing.
19. **Home Spirometry**	09-E0000-36	Review: Position statement maintained; description and references updated.
20. **Hospice Care**	01-99500-03	Review; no change in position statement.
21. **Investigational Services**	09-A0000-03	Code A4540 deleted (refer to policy 02-61000-03).
22. **Knee Braces**	09-L0000-01	Review: Prophylactic braces position statement updated to include "rehabilitative"; references updated.
23. **Magnetic Resonance Imaging (MRI) Orbit, Face, Temporomandibular Joint (TMJ) and Neck**	04-70540-12	Review; no change in position statement. Updated references.
24. **Mirikizumab-mrkz (Omvoh®) Injection and Infusion**	09-J4000-71	Revision to guideline consisting of updating the position statement and other section. Tremfya added as Step 1a agent for UC and clarified that the age requirement that exists for subcutaneous Omvoh also applies to intravenous Omvoh.

25. **Mogamulizumab-kpkc (Poteligeo) Injection**	09-J3000-05	Review and revision to guideline; consisting of updating the use for Adult T-cell leukemia/lymphomas, Mycosis fungoides (MF)/ Sézary syndrome (SS) and updating references.
26. **Molecular Testing for the Management of Pancreatic Cysts and Solid Pancreaticobiliary Lesions**	05-86000-27	Review: Title, position statement, description, and references updated. Refer to policy 05-87000-01 for BarreGEN test.
27. **Occipital Nerve Stimulation**	02-61000-06	Scheduled review. Revised description, maintained position statement and updated references.
28. **Oral Oncology Medications**	09-J3000-65	Review and revision to guideline; addition of Lazcluze and Voranigo tablets to Table 1.
29. **Ozanimod (Zeposia) Capsules**	09-J3000-70	Revision to guideline consisting of updating the position statement and other section. Tremfya added among the required prerequisite agents for Zeposia for UC.
30. **Palovarotene (Sohonos) Oral Capsules**	09-J4000-66	Review and revision to the guideline consisting of revising the position statement to avoid use in patients with moderate hepatic impairment (Child-Pugh B) and updated references.
31. **Percutaneous and Subcutaneous Tibial Nerve Stimulation**	02-64000-01	Review: Position statements maintained; description and references updated.
32. **Percutaneous Electrical Nerve Stimulation (PENS)**	02-61000-03	Revision. Revised description, added coverage statement for remote electrical neuromodulation (REN) (eg, Nerivio®), added code A4540, and updated references.

33. **Photocoagulation of Macular Drusen**	01-92000-21	Scheduled review. Revised description, maintained position statement and updated references.
34. **Positron Emission Tomography (PET) Miscellaneous Applications**	04-78000-18	Added code (78811, 78812, 78813, 78814, 78815, 78816). Revised position statement.
35. **Private Duty Nursing Care in the Home**	01-99500-02	Review; no change in position statement.
36. **Radiofrequency Ablation of Solid Tumors Other Than Liver Tumors**	02-99221-13	Review; no change in position statement. Updated references.
37. **Radiofrequency and Microwave Ablation of Liver Tumors**	02-40000-23	Scheduled review. Revised description, maintained position statement and updated references.
38. **Sacroiliac Joint Injections**	02-20000-21	Scheduled review. Revised description, maintained position statement and updated references.
39. Scintimammography and Gamma Imaging of the Breast	04-78000-14	Review; no change in position statement. Updated references.
40. **Tocilizumab (Actemra) Injection and Infusion, Tocilizumab-aazg (Tyenne) Injection and Infusion, and Tocilizumab-bavi (Tofidence) Infusion**	09-J1000-21	Revision to guideline consisting of updating the position statement, other section, and billing/coding. HCPCS code Q5135 applies to both IV and SC Tyenne. The applicable ICD-10 code depends on if Tyenne is SC or IV.
41. **Transanal Radiofrequency Therapy as a Treatment of Fecal Incontinence**	01-91000-07	Scheduled review. Revised description, maintained position statement and updated references.
42. **Transtympanic Micropressure Applications as a Treatment of Meniere's Disease**	09-E0000-46	Review: Position statement maintained; description and references updated.
43. **Ustekinumab (Stelara) Injection and Infusion**	09-J1000-16	Revision to guideline consisting of updating the position statement to clarify that the age requirement that exists for

		subcutaneous Stelara also applies to intravenous Stelara.
44. **Vedolizumab (Entyvio) Injection and Infusion**	09-J2000-18	Revision to guideline consisting of updating the position statement and other section. Tremfya added as Step 1a agent for UC.
45. **Vestibular Rehabilitation**	01-92502-14	Scheduled review. Revised description, maintained position statement and updated references.
46. **Whole Body Computed Tomography (CT)**	04-70450-25	Review; no change in position statement. Updated references.
47. **Whole Body Dual X-ray Absorptiometry (DEXA) to Determine Body Composition and Other Body Composition Techniques**	04-70000-22	Review; no change to position statement. Updated 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 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.