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: 7/1/2024

New and Revised MCGs:	MCG Number	Update
1. Abatacept (Orencia) Injection and Infusion	09-J0000-67	Revision to guideline consisting of updating the position statement, related guidelines, and other section. Amjevita low-concentration removed as a required prerequisite agent. Updates to the positioning of agents in Table 1. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
2. Abrocitinib (Cibinqo) Tablets	09-J4000-27	Revision to guideline consisting of updating the position statement and other section. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
3. Adalimumab Products (Humira and biosimilars)	09-J0000-46	Revision to guideline consisting of updating the description section, position statement, dosage/administration, billing/coding, related guidelines, other section, and references. Amjevita low-concentration moved from a Step 1 agent to a non-preferred Step 3c agent. Simlandi added to the policy as a Step 3c agent with Hadlima and Humira as required prerequisites. Rinvoq is a new Step 1b agent for PJIA. Removal of latent TB testing requirement.

		New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
4. ADAMTS13, recombinant-krhn (Adzynma) IV Infusion	09-J4000-75	Revision: Added HCPCS code J7171 and deleted codes C9167 and J3590.
5. Anakinra (Kineret) Injection	09-J0000-45	Revision to guideline consisting of updating the position statement, related guidelines, and other section. Amjevita low-concentration removed as a required prerequisite agent. Updates to the positioning of agents in Table 1. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
6. Analysis of Human DNA as a Technique for Colorectal Cancer Screening	05-82000-27	Quarterly CPT/HCPCS coding update. Code 0464U added.
7. Apremilast (Otezla) Tablet	09-J2000-19	Revision to guideline consisting of updating the description, position statement, related guidelines, other section, and references. Updates to the positioning of agents in Table 1. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
8. Baricitinib (Olumiant) Tablet	09-J3000-10	Revision to guideline consisting of updating the position statement, related guidelines, and other section. Amjevita low-concentration removed as a required prerequisite agent. Updates to the positioning of agents in Table 1. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
9. Betibeglogene Autotemcel (Zynteglo) IV Infusion	09-J4000-35	Revision: Added HCPCS code J3393 and deleted code J3590.
10. Bimekizumab-bkzx (Bimzelx) Injection	09-J4000-70	Revision to guideline consisting of updating the position statement, related guidelines,

		and other section. Amjevita low-concentration removed as a required prerequisite agent. Updates to the positioning of agents in Table 1. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
11. Bio-Engineered Skin and Soft Tissue Substitutes, Amniotic Membrane and Amniotic Fluid	02-10000-11	Quarterly CPT/HCPCS coding update. Codes Q4311-Q4333 added; codes Q4210, Q4277 deleted.
12. Brodalumab (Siliq) Injection	09-J2000-79	Revision to guideline consisting of updating the description, position statement, related guidelines, and other section. Amjevita low-concentration removed as a required prerequisite agent. Updates to the positioning of agents in Table 1. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
13. Certolizumab Pegol (Cimzia) Injection	09-J0000-77	Revision to guideline consisting of updating the description, position statement, related guidelines, and other section. Amjevita low-concentration removed as a required prerequisite agent. Updates to the positioning of agents in Table 1. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
14. Chimeric Antigen Receptor (CAR) T-Cell Therapies	09-J3000-94	Revision to guideline consisting of updating the description, position statement, dosage/administration, precautions, billing/coding, and references based on new FDA-approved indications for Breyanzi for relapsed or refractory FL and MCL. Updated description for HCPCS code Q2055.

15. Cooling and Heating Devices Used in the Outpatient Setting	09-E0000-53	Quarterly CPT/HCPCS coding update. Added 0881T.
16. Deucravacitinib (Sotyktu) Tablet	09-J4000-37	Revision to guideline consisting of updating the description, position statement, related guidelines, other section, and references. Sotyktu changed from a Step 3c agent (triple step) to a Step 2 agent (single step). Amjevita low-concentration removed as a preferred agent. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
17. Docetaxel (Taxotere) IV	09-J0000-95	Revision: Grammatical revision to HCPCS code J9172.
18. Dupilumab (Dupixent) Injection	09-J2000-80	Revision to guideline consisting of updating the position statement and other section. Drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
19. Etanercept (Enbrel) Injection	09-J0000-38	Revision to guideline consisting of updating the description section, position statement, related guidelines, and other section. New indication for juvenile psoriatic arthritis. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
20. Etrasimod (Velsipity) Tablet	09-J4000-72	Revision to guideline consisting of updating the position statement, related guidelines, and other section. Amjevita low-concentration removed as a required prerequisite agent. Updates to the positioning of agents in Table 1. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.

21. Genetic Testing	05-82000-28	Quarterly CPT/HCPCS coding update. Codes 0460U, 0461U, 0469U, 0475U added.
22. Golimumab (Simponi, Simponi Aria) Injection and Infusion	09-J1000-11	Revision to guideline consisting of updating the position statement, related guidelines, and other section. Amjevita low-concentration removed as a required prerequisite agent. Updates to the positioning of agents in Table 1. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
23. Granulocyte Colony Stimulating Factors	09-J0000-62	Revision: Added HCPCS code J9361 and deleted code J3590.
24. Guselkumab (Tremfya) Injection	09-J2000-87	Revision to guideline consisting of updating the description, position statement, related guidelines, and other section. Updates to the positioning of agents in Table 1. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
25. Infliximab Products	09-J0000-39	Revision to guideline consisting of updating the description, position statement, dosage/administration, billing/coding, related guidelines, other section, and references. Zymfentra added to the guidelines as a non-preferred, self-administered Step 3c (triple stepped) agent for CD and UC. Position statement divided into one section for "SUBCUTANEOUS INFLIXIMAB PRODUCTS (PHARMACY BENEFIT)" and one section for "INTRAVENOUS INFLXIMAB PRODUCTS (MEDICAL BENEFIT)" as criteria are different. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy. New HCPCS code for Zymfentra.

26. Investigational Services	09-A0000-03	Quarterly CPT/HCPCS coding update. Codes 0456U, 0894T, 0895T, 0896T added; code 0714T revised.
27. Ixekizumab (Taltz) Injection	09-J2000-62	Revision to guideline consisting of updating the description, position statement, related guidelines, and other section. Amjevita low concentration removed as a required prerequisite agent. Updates to the positioning of agents in Table 1. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
28. Lovotibeglogene autotemcel (Lyfgenia) suspension for IV infusion	09-J4000-83	Revision: Added HCPCS code J3394 and deleted code J3590.
29. Mirikizumab-mrkz (Omvoh®) Injection and Infusion	09-J4000-71	Revision to guideline consisting of updating the position statement, related guidelines, and other section. Amjevita low-concentration removed as a required prerequisite agent. Updates to the positioning of agents in Table 1. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy. Added HCPCS code J2267 and deleted code C9168.
30. Nab-Paclitaxel Injection (Abraxane)	09-J1000-05	Revision: Revision to HCPCS codes J9258 and J9259.
31. New To Market Program	09-J4000-30	Removed Winrevair (sotatercept-csrk) from the drug list.
32. Ozanimod (Zeposia) Capsules	09-J3000-70	Revision to guideline consisting of updating the position statement, related guidelines, and other section. Amjevita low-concentration removed as a required prerequisite agent for UC. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.

33. Pemetrexed (Alimta, Pemfexy) IV	09-J1000-01	Revision: Grammatical revision to HCPCS codes.
34. Pulmonary Hypertension Drug Therapy	09-J1000-12	Review and revision to guideline; consisting of updating references and position statement.
35. Risankizumab-rzaa (Skyrizi) Injectionand Infusion	09-J3000-45	Revision to guideline consisting of updating the description section, position statement, guidelines, and other section. Updates to the positioning of agents in Table 1. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
36. Ritlecitinib (Litfulo) Capsule	09-J4000-57	Revision to guideline consisting of updating the position statement, and other section. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
37. Sarilumab (Kevzara) Injection	09-J2000-88	Revision to guideline consisting of updating the description, position statement, related guidelines, and other section. Amjevita low-concentration removed as a required prerequisite agent. Updates to the positioning of agents in Table 1. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
38. Secukinumab (Cosentyx) Injection and Infusion	09-J2000-30	Revision to guideline consisting of updating the description section, position statement, related guidelines, and other section. Updates to the positioning of agents in Table 1. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy. Added HCPCS code J3247 and deleted code C9166.

39. Site of Care Guideline for Select Specialty Medications	09-J3000-46	Revision to guideline consisting of updating the position statement, billing/coding, and related guidelines based on the additions of Tofidence and Tyenne.
40. Teriparatide (Forteo)	09-J0000-47	Review and revision to guideline; consisting of requiring a step through generic teriparatide for the brand product.
41. Tildrakizumab-asmn (Ilumya)	09-J3000-04	Revision to guideline consisting of updating the description section, position statement, related guidelines. and other section. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
42. 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 description, position statement, dosage/administration, billing/coding, other section, and references. Added tocilizumab-aazg (Tyenne) IV infusion to guideline, the second biosimilar to Actemra IV. It is covered at parity with IV Actemra and IV Tofidence with the same indications and criteria. Amjevita low-concentration removed as a preferred agent. Rinvoq added as a Step 1b product for PJIA. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
43. Tofacitinib (Xeljanz, Xeljanz XR) Oral Solution, Tablet and Extended-Release Tablet	09-J1000-86	Revision to guideline consisting of updating the position statement, related guidelines, and other section. Amjevita low-concentration removed as a required prerequisite agent. Updates to the positioning of agents in Table 1. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.

44. Tralokinumab-ldrm (Adbry) Injection	09-J4000-20	Revision to guideline consisting of updating the position statement and other section. Approval duration for new starts is 12 months. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
45. Tumor/Genetic Markers	05-86000-22	Quarterly CPT/HCPCS coding update. Code 0204U deleted.
46. Upadacitinib Tablets (Rinvoq) and Oral Solution (Rinvoq LQ)	09-J3000-51	Revision to guideline consisting of updating the description section, position statement, dosage/administration, related guidelines, billing/coding, definitions, other section, and references. New FDA-approved indication for PJIA and age expanded to 2 years and older for psoriatic arthritis. New liquid formulation, Rinvoq LQ, approved for use. Amjevita low-concentration removed as a required prerequisite agent. Updates to the positioning of agents in Table 1. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
47. Ustekinumab (Stelara) Injection and Infusion	09-J1000-16	Revision to guideline consisting of updating the description section, position statement, related guidelines, and other section. Updates to the positioning of agents in Table 1. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
48. Vedolizumab (Entyvio) Injection and Infusion	09-J2000-18	Revision to guideline consisting of updating the description section, position statement. dosage/administration, billing/coding, related guidelines, other section, and references. Entyvio SC for UC was changed from a Step 3c agent to a Step 3b agent (i.e., now stepped though two preferred agents vs. three). Amjevita low-concentration removed as a preferred agent. New indication of CD added for Entyvio SC (Step 3b). Removal of latent TB

		testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.

What's New: 6/15/2024

New and Revised MCGs:	MCG Number	Update
1. Amivantamab-vmjw (Rybrevant)	09-J4000-02	Revision to guideline; updated position statement and dosing (NCCN).
2. Birch Triterpenes (Filsuvez)	09-J4000-87	New Medical Coverage Guideline.
3. Computed Tomographic Angiography (CTA) Heart	04-70450-03	Review; no change in position statement. Updated references.
4. Computed Tomography to Detect Coronary Artery Calcification	04-70450-02	Review; no change in position statement. Updated program exceptions and references.
5. Continuous Passive Motion Device	09-E0000-15	Review: Position statements maintained; description and references updated.
6. Danicopan (Voydeya)	09-J4000-88	New Medical Coverage Guideline.
7. Delandistrogene moxeparvovec (Elevidys)	09-J4000-53	New Medical Coverage Guideline.
8. Drugs and Biologics without Medical Coverage Guideline	09-J0000-68	Review and revision to guideline; added iDose TR, Tevimbra, and Quzyttir to table 1.
9. Evoked Potentials, Intraoperative Neurophysiologic Monitoring, and Quantitative Electroencephalography (QEEG)	01-95805-13	Review: Position statements maintained; description and references updated.
10. In Vitro Chemoresistance and Chemosensitivity Assays	05-86000-11	Review: Position statements maintained; description and references updated.
11. Infertility	02-56000-24	Review; no change in position statement. Updated references

12. Injectable Iron Therapy	09-J2000-10	Revised position statement to update lab requirements for IDA.
13. Irinotecan Liposome Injection (Onivyde)	09-J2000-52	Review and revision to guideline consisting of updating the position statement to include the FDA indication and NCCN recommendations for pancreatic cancer for first-line therapy or induction therapy followed by chemoradiation in combination with oxaliplatin, fluorouracil and leucovorin as well as updating dosing and references.
14. Irreversible Electroporation (IRE)	02-40000-26	Scheduled review. Revised description. Maintained position statement and updated references.
15. Knee Arthroplasty	02-20000-60	Scheduled review. Revised description. Maintained position statement and updated references.
16. Knee Arthroscopy and Open, Non-Arthroplasty Knee Repair	02-20000-65	Scheduled review. Revised description. Maintained position statement and updated references.
17. Laser Vitreolysis	02-65000-14	Revised description and updated references.
18. Lecanemab-irmb (Leqembi) intravenous infusion	09-J4000-41	Update HCPCS coding from J3590 to J0174.
19. Magnetic Resonance Imaging of the Breast	04-70540-09	Review; no change in position statement. Updated references.
20. Maralixibat (Livmarli)	09-J4000-10	Revision to guidelines consisting of updates to the description, position statement, dosage/administration, precautions, billing/coding, and references based on the new FDA-approved indication for PFIC.
21. Mechanical Stretching Devices for Treatment of Joint Stiffness and Contractures	09-E0000-47	Review: Position statements maintained; description and references updated.
22. Myoelectric Prosthetic and Orthotic Components for the Upper Limb	09-L0000-07	Review: Position statements maintained; description and references updated.

23. Neurolysis, Ablation	02-61000-34	Revision. Updated criteria for controlled medial branch blocks.
24. New To Market Program	09-J4000-30	Removed Elevidys (delandistrogene moxeparvovec-rokl from the drug list.
25. Nivolumab, Relatlimab-rmbw (Opdualag) injection	09-J4000-23	Review and revision to guideline; consisting of updating position statement to include neoadjuvant treatment.
26. Non-Covered Services	09-A0000-00	Added code S9988.
27. Non-Invasive Electrical Bone Growth Stimulators (EBGS)	09-E0000-22	Review; no change in position statement. Updated references.
28. Oxaliplatin (Eloxatin) Injection	09-J1000-00	Policy retired.
29. Radiation Treatment Delivery and Radiation Treatment Management - Reimbursement Guideline	04-77260-01	Review; Deleted intraoperative radiation therapy. Updated references.
30. Resmetirom (Rezdiffra) tablets	09-J4000-85	New Medical Coverage Guideline – Resmetirom (Rezdiffra) tablets in conjunction with diet and exercise for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis (NASH)/noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) with moderate to advanced liver fibrosis.
31. Step Therapy Requirements for Medicare Outpatient (Part B) Medications	09-J3000-39	Revision to guidelines, consisting of the addition of non-preferred drugs Prolia and Evenity.
32. Subtalar Arthroereisis	02-99221-17	Review: Position statement maintained; description and references updated.
33. Therapeutic Radiology Simulation-Aided Field Setting Reimbursement Guideline	04-77260-05	Review; no change to position statement. Updated references.
34. Therapeutic Radiology Treatment Planning Reimbursement Guideline	04-77260-04	Review; no change to position statement. Updated references.

35. Thoracic and Lumbar Spine Surgery	02-20000-48	Scheduled review. Revised description. Maintained position statement and updated references.
36. Transvaginal Radiofrequency Bladder Neck Suspension and Transurethral Radiofrequency Tissue Remodeling for Urinary Stress Incontinence	02-50000-16	Review; no change in 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
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

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

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.