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: 7/15/2025

New and Revised MCGs:	MCG Number	Update
1. Acoramidis (Attruby)	09-J5000-11	Revision to guideline; updated position statement
2. Alemtuzumab (Lemtrada) IV	09-J2000-27	Review and revision to guideline; consisting of updating the warnings and references.
3. Amniotic Membrane and Limbal Stem Cell Transplantation for the Treatment of Ocular Conditions	02-65000-19	Scheduled review. Revised description, maintained position statement, and updated references.
4. Aqueous Shunts and Stents for Glaucoma	01-92000-24	Scheduled review. Maintained position statement and updated references.
5. Biofeedback	01-90900-01	Scheduled review. Maintained position statement and updated references.
6. Brand (Aubagio) Tablet	09-J1000-82	Review and revision to guideline; consisting of updating the references.
7. Brand Gilenya Capsule and Tascenso ODT	09-J1000-30	Update to dosing, warnings, and references.

8. Brand Tecfidera, Diroximel fumarate (Vumerity), Monomethyl fumarate (Bafiertam) Capsule	09-J1000-96	Review and revision to guideline; consisting of updating the warnings and references.
9. Buprenorphine (Brixadi, Sublocade) Subcutaneous Injection	09-J2000-68	Revision; updated position statement with FDA label recommendations for initiation of therapy
10. Carfilzomib (Kyprolis) Injection	09-J1000-81	Review and revision to guidelines consisting of updating the description section, position statement, and references. Added indication of POEMS syndrome (carfilzomib as a replacement for bortezomib in select patients). Added new regimen of carfilzomib + isatuximab, lenalidomide, and dexamethasone for patients who are transplant candidates.
11. Cladribine (Mavenclad) tablets	09-J3000-34	Review and revision to guideline; consisting of updating the warnings and references.
12. Clotting Factors and Coagulant Blood Products	09-J0000-34	Revision to position statement.
13. Computed Tomography (CT) Head and Brain	04-70450-18	Review; no change in position statement.
14. Computed Tomography (CT) of the Neck for Soft Tissue Evaluation	04-70450-20	Review; no change in position statement.
15. Computed Tomography (CT) Temporal Bone/Mastoid & Maxillofacial	04-70450-19	Review; no change in position statement.
16. Computed Tomography (CT) Thorax (Chest)	04-70450-21	Review; no change in position statement.
17. Computer-Assisted Navigation for Orthopedic Procedures	02-20000-30	Review: Position statement maintained and references updated.
18. Corticosteroid Intravitreal Implant	09-J2000-35	Revision to guideline consisting of updating the position statement to include the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye for Iluvien, revising the

		warning section for Iluvien to include delayed healing and corneal and scleral melting, and updating the diagnosis codes and references.
19. **Daratumumab (Darzalex) Infusion and Daratumumab-Hyaluronidase-fihj (Darzalex Faspro) Injection**	09-J2000-49	Review and revision to guidelines consisting of updating the description section, position statement, related guidelines, and references. Added coverage for POEMS syndrome per new NCCN inclusion. Added new combination regimens for multiple myeloma and systemic light chain amyloidosis per NCCN updates.
20. **Deep Brain Stimulation and Responsive Neurostimulation**	02-61000-24	Review: Position statements maintained and references updated.
21. **Elotuzumab (Empliciti) Injection**	09-J2000-50	Review and revision to guideline consisting of updating the description, position statement, and references. For elotuzumab + pomalidomide + dexamethasone regimen, updated the prerequisite requirements to two prior lines of therapy including lenalidomide and a proteasome inhibitor.
22. **Elranatamab-bcmm (Elrexfio) Subcutaneous Injection**	09-J4000-64	Review and revision to guideline consisting of updating the description section and references.
23. **Eplontersen (Wainua)**	09-J4000-77	Revision to guideline; updated position statement.
24. **Eptinezumab-jjmr (Vyepti)**	09-J3000-68	Review and revision to guideline; updated references.
25. **Erythropoiesis Stimulating Agents**	09-J0000-31	Review and revision to guideline; consisting of including Epogen as one of the preferred agents with Procrit and Retacrit.

26. **Esketamine (Spravato) Nasal Spray**	09-J3000-37	Review and revision of the guideline consisting of updating the position statement to reduce the trial of prior antidepressant medications for treatment-resistant depression from three to two agents from different drug classes
27. **Foscarbidopa-Foslevodopa (Vyalev) subcutaneous infusion**	09-J5000-09	Review and revision to guideline consisting of revising the position statement to allow in consultation with a specialist who treats Parkinson's disease.
28. **Functional Neuromuscular Stimulation**	09-E0000-54	Review; add position statement for functional electrical stimulation (FES) and spinal cord injury. Updated references.
29. **Ganaxolone (Ztalmy) Oral Suspension**	09-J4000-39	Review and revision to guideline consisting of updating the references.
30. **Genetic Testing**	05-82000-28	References updated.
31. **Heart and Lung Transplant**	02-33000-24	Scheduled review. Revised description, maintained position statement and updated references.
32. **High Resolution Anoscopy**	02-46000-01	Review: Position statements maintained; references updated.
33. **Home Pulse Oximetry**	09-E0000-49	Review: Position statements maintained and references updated.
34. **Implantable Bone-Conduction and Bone-Anchoring Hearing Aids**	02-69000-06	Review; no change to position statement. Updated reference.
35. **Intravenous Enzyme Replacement Therapy For Gaucher Disease**	09-J0000-41	Review and revision to guideline; consisting of updating references and position statement.
36. **Ipilimumab (Yervoy) Injection**	09-J1000-34	Revision to guideline; consisting of adding Adrenal tumors and updating colon, esophageal, and hepatocellular cancer.

37. **Isatuximab-irfc (Sarclisa) Infusion**	09-J3000-67	Review and revision to guideline consisting of updating the description, position statement, and references. Standardized the transplant candidate language. For the quadruplet regimen of isatuximab + lenalidomide + bortezomib + dexamethasone for transplant candidates, added requirements of less than 80 years of age and not frail (per NCCN guidelines).
38. **Isolated Small Bowel Transplant**	02-40000-18	Scheduled review. Maintained position statement and updated references.
39. **Ixazomib (Ninlaro) Capsule**	09-J2000-51	Review and revision to guidelines consisting of updating the description section, position statement, and references per NCCN updates. Ixazomib-containing regimens are no longer recommended by NCCN as primary therapy for transplant candidates. Use as primary therapy for non-transplant candidates is limited to when ixazomib is substituted for bortezomib or carfilzomib in select patients. Additional ixazomib-containing regimens were added for non-transplant candidates who have intolerable adverse effects to bortezomib or carfilzomib.
40. **Kidney Transplant**	02-50300-01	Scheduled review. Maintained position statement and updated references.
41. **Laparoscopic and Percutaneous Techniques for the Treatment of Uterine Fibroids**	02-56000-30	Review; no change in position statement. Updated references.
42. **Lifileucel (Amtagvi) suspension for IV infusion**	09-J4000-81	Review of the guideline to revise the position statement to allow for concomitant systemic corticosteroid for the treatment of life-threatening conditions (e.g., adrenal insufficiency).

43. **Manipulation Under Anesthesia**	02-20000-34	Scheduled review. Maintained position statement and updated references.
44. **Multiple Sclerosis Self Injectable Therapy (Interferon beta products and Copaxone)**	09-J1000-39	Review and revision to guideline; consisting of updating the warnings and references.
45. **Natalizumab (Tysabri) IV**	09-J0000-73	Review and revision to guideline; consisting of updating the warnings and references.
46. **Noninvasive Prenatal Screening Using Cell-Free Fetal DNA**	03-59000-18	Review: Position statement for RhD genotyping added; position statements and title updated; description, coding, and references updated.
47. **Ocrelizumab (Ocrevus, Ocrevus Zunovo) Infusion**	09-J2000-78	Review and revision to guideline; consisting of updating the warnings and references
48. **Ofatumumab (Kesimpta)**	09-J3000-84	Review and revision to guideline; consisting of updating the contraindications, warnings, and references.
49. **Omalizumab (Xolair, Omlyclo)**	09-J0000-44	Revision to guideline; updated position statement and coding.
50. **Oral Therapy for Gaucher and Pompe Disease**	09-J0000-76	Review and revision to guideline; consisting of updating references and position statement.
51. **Ozanimod (Zeposia) Capsules**	09-J3000-70	Review and revision to guideline; consisting of updating the warnings and references.
52. **Patisiran Sodium (Onpattro)**	09-J3000-16	Revision to guideline; updated position statement.
53. **Peanut (Arachis hypogaea) Allergen Powder-dnfd (Palforzia)**	09-J3000-69	Review and revision to guideline; updated position statement and references.

54. **Pegvaliase-pqpz (Palynziq)**	09-J3000-07	Review and revision to guideline; updated references.
55. **Pneumatic Compression Devices and Garments**	09-E0000-31	Revision. Updated references for treatment of head and neck lymphedema. Revised description. Maintained position statement.
56. **Ponesimod (Ponvory) Tablet**	09-J3000-98	Review and revision to guideline; consisting of updating the warnings and references.
57. **Prosthetic Eyes and Lens Implants**	09-V0000-01	Review; no change to position statement. Updated references.
58. **Quantitative Sensory Testing**	01-95805-18	Review: Position statement maintained and references updated.
59. **Sacral Nerve Neuromodulation/Stimulation**	02-61000-23	Review: Position statements maintained; coding and references updated.
60. **Siponimod (Mayzent) tablets**	09-J3000-35	Review and revision to guideline; consisting of updating the references.
61. **Small Bowel, Liver and Multivisceral Transplant**	02-40000-19	Scheduled review. Maintained position statement and updated references.
62. **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 Izervay [Ophthalmic Agents], non-preferred Focinvez, Cinvanti, Posfrea [Cancer and Supportive Therapy], non-preferred Imaavy [Complement Inhibitors] and removal of ST program [Erythropoiesis Stimulating Agents]
63. **Surgical Treatment of Occipital Neuralgia and Headache**	02-20000-41	Scheduled review. Revised description, maintained position statement and updated references.

64. **Tafamidis (Vyndamax, Vyndaqel) Oral**	09-J3000-41	Review and revision to guideline; updated position statement and references.
65. **Tafasitamab-cxix (Monjuvi) IV Infusion**	09-J3000-81	Review and revision to guideline consisting of updating the description, position statement, billing/coding, and references based on updated NCCN B-Cell Lymphoma guidelines. Added classic follicular lymphoma as a new indication which includes a new combination regimen of tafasitamab + lenalidomide + a rituximab product. Removed global requirement that the member does not intend to proceed to transplant. This requirement is now diagnosis specific and, for some diagnoses, based on the time of relapse.
66. **Talquetamab-tgvs (Talvey) Subcutaneous Injection**	09-J4000-63	Review and revision to guideline consisting of updating the description section, position statement and references. Added an allowance for the combination regimen of teclistamab and talquetamab based on inclusion in the NCCN recommendations for MM.
67. **Teclistamab (Tecvayli) Injection**	09-J4000-46	Review and revision to guideline consisting of updating the description section, position statement and references. Added an allowance for the combination regimen of teclistamab and talquetamab based on inclusion in the NCCN recommendations for MM.
68. **Thumb Basal Joint Arthroscopy**	02-20000-38	Scheduled review. Maintained position statement and updated references.
69. **Total Body Plethysmography**	01-94010-09	Review; no change in position statement.
70. **Trigger Point Injections**	02-20000-28	Scheduled review. Revised description, maintained position statement and updated references.

71. **Ublituximab-xiiy (Briumvi)**	09-J4000-45	Review and revision to guideline; consisting of updating the references.
72. **Viscocanalostomy and Canaloplasty**	02-65000-18	Scheduled review. Revised description. maintained position statement and updated references.
73. **Vutrisiran (Amvuttra)**	09-J4000-32	Revision to guideline; updated position statement

What's New: 7/1/2025

New and Revised MCGs:	MCG Number	Update
1. **Abatacept (Orencia) Injection and Infusion**	09-J0000-67	Revision: Added Selarsdi, Steqeyma and Yesintek among the preferred agents for PsA for Orencia SC.
2. **Aprocitentan (Tryvio) Tablets**	09-J5000-18	New Medical Coverage Guideline: Aprocitentan (Tryvio) for the treatment of resistant hypertension in combination with at least three antihypertensive medications from different classes at maximally tolerated doses.
3. **Atidarsagene autotemcel (Lenmeldy) suspension for IV infusion**	09-J4000-84	Revision: Added HCPCS code J3391 and deleted code J3590.
4. **Atrasentan (Vanrafia) tablet**	09-J5000-20	New Medical Coverage Guideline.
5. **Bimekizumab-bkzx (Bimzelx) Injection**	09-J4000-70	Revision: Added Selarsdi, Steqeyma and Yesintek among the preferred agents for PS and PsA.
6. **Bio-Engineered Skin and Soft Tissue Substitutes, Amniotic Membrane and Amniotic Fluid**	02-10000-11	Quarterly CPT/HCPCS coding update. Codes Q4368-Q4382 added.

7. **Brodalumab (Siliq) Injection**	09-J2000-79	Revision: Added Selarsdi, Steqeyma and Yesintek among the preferred agents for PS.
8. **Certolizumab Pegol (Cimzia) Injection**	09-J0000-77	Revision: Added Selarsdi, Steqeyma and Yesintek among the preferred agents for CD, PS, and PsA for for self-administered Cimzia.
9. **Chenodiol (Ctexli) Tablets**	09-J5000-16	New Medical Coverage Guideline: Chenodiol (Ctexli), a bile acid, for the treatment of cerebrotendinous xanthomatosis (CTX) in adults.
10. **Chimeric Antigen Receptor (CAR) T-Cell Therapies**	09-J3000-94	Revision: Added HCPCS code Q2058 and removed codes C9301 and J9999.
11. **Datopotamab Deruxtecan (Datroway) IV Infusion**	09-J5000-19	Revision: Added HCPCS code C9174.
12. **Diazoxide Choline (Vykat XR) Tablet**	09-J5000-21	New Medical Coverage Guideline.
13. **Docetaxel Products**	09-J0000-95	Revision to guideline, updated position statement and coding.
14. **Efgartigimod alfa-fcab (Vyvgart, Vyvgart Hytrulo) injection**	09-J4000-18	Update to position statement to include Vyvgart Hytrulo prefilled syringe and updated agents not to be used in combination.
15. **Etrasimod (Velsipity) Tablet**	09-J4000-72	Revision: Added Selarsdi, Steqeyma and Yesintek among the preferred agents for UC.
16. **Foscarbidopa-Foslevodopa (Vyalev) subcutaneous infusion**	09-J5000-09	Revision: Added HCPCS code J7356 and deleted codes C9399 and J3490.
17. **Golimumab (Simponi, Simponi Aria) Injection and Infusion**	09-J1000-11	Revision: Added Selarsdi, Steqeyma and Yesintek among the preferred agents for PsA for Simponi.

18. **Gonadotropin Releasing Hormone Analogs and Antagonists**	09-J0000-48	Revision: Revised description of HCPCS code J1954. Cipla product is now Lutrate Depot from Avyxa Pharma.
19. **Implantable Cardioverter Defibrillators/Cardiac Contractility Modulation (CCM) Therapy**	02-33000-34	Quarterly CPT/HCPCS coding update. Codes 0948T, 0949T added.
20. **Inclisiran (Leqvio) Injection**	09-J4000-21	Review and revision to guidelines consisting of updates to the position statement and references. Simplified the criteria for the 10-year ASCVD risk ≥20% indications, and the criteria for statin intolerance.
21. **Infliximab Products [infliximab (Remicade), infliximab-dyyb (Inflectra), infliximab-abda (Renflexis), and infliximab-axxq (Avsola)]**	09-J0000-39	Revision: Added Selarsdi, Steqeyma and Yesintek among the preferred agents for CD and UC for Zymfentra SC.
22. **Injectable Bulking Agents for Treatment of Urinary and Fecal Incontinence**	09-A9000-03	Quarterly CPT/HCPCS coding update. Added 0963T.
23. **Ixekizumab (Taltz) Injection**	09-J2000-62	Revision: Added Selarsdi, Steqeyma and Yesintek among the preferred agents for PS and PsA.
24. **Lebrikizumab-lbkz (Ebglyss) Injection**	09-J5000-00	Revision to guidelines consisting of updates to the description section, position statement, and related guidelines. The step through other biologic agents for atopic dermatitis was removed.
25. **Medical & Surgical Management of Sleep Apnea, Snoring, and Other Conditions of the Soft Palate and Nasal Passages**	02-40000-16	Quarterly CPT/HCPCS coding update. Codes 0964T-0966T added.
26. **Mirikizumab-mrkz (Omvoh®) Injection and Infusion**	09-J4000-71	Revision: Added Selarsdi, Steqeyma and Yesintek among the preferred agents for CD and UC.

27. **Nemolizumab-ilto (Nemluvio) Injection**	09-J4000-99	Revision to guidelines consisting of update to the description section, position statement, dosage/administration, definitions, related guidelines, billing/coding, and references. New indication of moderate-to-severe atopic dermatitis added.
28. **New-To-Market Program for Medical Benefit Medications**	09-J4000-30	Added Bomyntra (denosumab-bnht) and Conexxence (denosumab-bnht) SC injections, and removed Wezlana (ustekinumab-auub), Otulfi (ustekinumab-aauz), Pyzchiva (ustekinumab-ttwe) and Imuldosa (ustekinumab-srlf) SC injections and IV infusions from the drug list. Added HCPCS code for Tepylute.
29. **Nivolumab products (Opdivo, Opdivo Qvantig)**	09-J2000-33	Revision: Added HCPCS code J9289 and removed code J9999.
30. **Omalizumab (Xolair, Omlyclo)**	09-J0000-44	Revision to guideline; updated position statement
31. **Ozanimod (Zeposia) Capsules**	09-J3000-70	Revision: Added Adalimumab-aaty, Adalimumab-adaz, Entyvio SC, Selarsdi, Steqeyma and Yesintek among the preferred agents for UC. New link to the list of biologic immunomodulator agents not permitted as concomitant therapy.
32. **Pemetrexed (Alimta, Axtle, Pemfexy, Pemrydi RTU) IV**	09-J1000-01	Revision: Revised description of HCPCS code J9292.
33. **Preferred Agents Table and Drug List**	09-J9000-01	Revision. The biosimilars of Selarsdi, Steqeyma, and Yesintek added among the preferred self-administered ustekinumab products that also still includes Stelara. The table now only references “ustekinumab product(s)”. Rinvoq added as a Step 1a agent for GCA. For Actemra SC, Tyenne SC is the required Step 1 agent for GCA.

34. **Preventive Services**	01-99385-03	Revision/update. Revised USPSTF recommendation for screening for obesity in children and adolescents 6 years or older. Annual HCPCS code update. Added 90635.
35. **Subcutaneous Prophylactic Therapy for Hemophilia (Non-Clotting Factor)**	09-J5000-12	Revised position statement. Added HCPCS code J7172.
36. **Tolvaptan (Jynarque) Tablet**	09-J3000-09	Review and revision to guideline consisting of revising the position statement to remove documentation requirements, changing kidney function requirements to no stage 5 CKD or dialysis, and expanding specialist prescribers and updating the references.
37. **Ublituximab-xiiy (Briumvi)**	09-J4000-45	Review and revision to guideline; consisting of updating the position statement to remove step requirement.
38. **Upadacitinib Tablets (Rinvoq) and Oral Solution (Rinvoq LQ)**	09-J3000-51	Revision to guideline consisting of updating the description section, position statement, dosage/administration, precautions, billing/coding, and references. New FDA-approved indication for GCA in adults. Rinvoq is a Step 1a agent for GCA.
39. **Ustekinumab Products (Stelara and Biosinilars)**	09-J1000-16	Revision to guideline consisting of updating the description section, position statement, dosage/administration, precautions, billing/coding, and references. Selarsdi, Stelara, Steqeyma and Yesintek are the co-preferred SC and IV ustekinumab products. Unbranded Ustekinumab SC (provider-administered) and IV is also a co-preferred product on the medical benefit only.

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

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.