[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: 12/15/2025

New and Revised MCGs:	MCG Number	Update
1. Afamelanotide (Scenesse) implant	09-J4000-38	Review and revision of the guideline, consisting of updating the references.
2. Autologous Chondrocyte Implantation (ACI)	02-20000-17	Revision. Revised description, added coverage statement for synthetic resorbable polymers/scaffolds (eg, AGILI-C®), and updated references.
3. Belantamab Mafodotin-blmf (Blenrep) IV Infusion	09-J3000-80	MCG reactivated due to Blenrep being re-approved by the FDA, in combination with bortezomib and dexamethasone, for the treatment of adult patients with relapsed or refractory MM who have received at least 2 prior lines of therapy, including a proteasome inhibitor and an immunomodulatory agent.
4. Brachytherapy-Oncologic Applications	04-77260-20	Review; revised endobronchial brachytherapy. Updated references.
5. Cardiac Monitoring Devices	01-93000-05	Review: Position statements maintained; description and references updated.
6. Clotting Factors and Coagulant Blood Products	09-J0000-34	Revision to position statement.

7. **Daratumumab (Darzalex) Infusion and Daratumumab-Hyaluronidase-fihj (Darzalex Faspro) Injection**	09-J2000-49	Revision to guidelines consisting of updating the description section, position statement, dosage/administration, definitions, and references. The FDA approved a new indication for Darzalex Faspro for the treatment of adult patients with high-risk smoldering MM as monotherapy.
8. **Denosumab Products (Prolia,Xgeva and biosimilars)**	09-J1000-25	Review and revision to guideline; consisting of updating the position statement to include additional biosimilars.
9. **Dopamine Transporter Imaging with Single-Photon Emission Computed Tomography**	04-78000-23	Review; no change to position statement. Updated references.
10. **Eltrombopag (Promacta, Alvaiz)**	09-J1000-13	Review and revision to guideline; consisting of adding a step through generic eltrombopag into the position statement.
11. **Exagamglogene autotemcel (Casgevy) suspension for IV infusion**	09-J4000-82	Review and revision of guideline consisting of revising the position statement to allow a history of receiving 10 units or more of pRBCs per year in the previous two years as a third option to define transfusion-dependent beta-thalassemia.
12. **Fecal Analysis in the Diagnosis of Intestinal Dysbiosis**	05-82000-33	Review; Policy archived.
13. **Ingestible pH and Pressure Capsule**	01-91000-08	Review; no change in position statement.
14. **Microwave Tumor Ablation Other Than Liver Tumors**	02-99221-18	Review; no change in position statement. Updated references.
15. **Natalizumab (Tysabri, Tyruko) IV**	09-J0000-73	Review and revision to guideline; consisting of adding Tyruko and updating coding and references.

16. **Nerve Conduction Studies; F-Wave Studies; H- Reflex Studies**	01-95805-02	Review; no change in position statement. Updated references.
17. **Non-Covered Services**	09-A0000-00	Scheduled review. Existing coding maintained.
18. **Olezarsen Sodium (Tryngolza) SQ Injection**	09-J5000-07	Review and revision to the guideline, consisting of revising the position statement to allow for inconclusive FCS genetic testing results with FCS scoring and expanded specialist prescribers and updating references.
19. **Olipudase Alfa-rpcp (Xenpozyme)**	09-J4000-34	Review and revision to guideline; updated references.
20. **Omaveloxolone (Skyclarys) Oral Capsule**	09-J4000-49	Review and revision of the guideline, consisting of revising the position statement to allow in consultation with a specialist for prescribing and updating the references.
21. **Proton Beam Therapy**	04-77260-18	Review; no change in position statement. Updated references.
22. **Pyrimethamine (Daraprim)**	09-J2000-48	Review and revision to guideline consisting of updating references
23. **Reconstructive Surgery/Cosmetic Surgery**	02-12000-01	Review; no change to position statement.
24. **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 the position statement to include Truxima as a co-preferred biosimilar with Ruxience and Riabni. Update to myasthenia gravis, liver transplant, hematopoietic cell transplant, compendia supported diagnoses, and inclusion of alternate dosing.
25. **Teriparatide (Forteo, Bonsity, Teriparatide Injection)**	09-J0000-47	Review and revision to guideline; consisting of updating the position

		statement to include Bonsity and a step through generic teriparatide for continuation.
26. **Velmanase alfa-tycv (Lamzede) intravenous infusion**	09-J4000-50	Review and revision of the guideline, consisting of updating the references.
27. **Wireless Capsule Endoscopy**	01-91000-05	Review and update. No change to position statement. Updated code 91111.

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

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.