09-J3000-46

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Reviewed: 05/13/26

Revised: 09/01/26

Subject: Site of Care Guideline for Select Non-Oncology Medications

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Program Exceptions	Definitions
Related Guidelines	Other	References	Updates

DESCRIPTION:

To ensure delivery of quality and affordable care, members will be directed to receive select provider-administered non-oncology medications at a cost-effective, clinically appropriate site of care. A preferred, cost-effective site of care includes a home infusion agency, professional office setting, or non-hospital-affiliated outpatient infusion facility. Requests for select non-oncology medications administered in a hospital-affiliated outpatient setting (i.e., place of service code 19 and 22) will be redirected to a preferred site of care unless criteria for medically necessity is met. The medication requested to be administered in a hospital-affiliated outpatient setting included in this guideline must meet both drug-specific medical coverage guideline (MCG) criteria and site of care requirements. Products appropriate for self-administration or administration by a caregiver (i.e., not a healthcare professional) are not considered medically necessary in either a hospital-affiliated outpatient setting or a provider-administered setting.

POSITION STATEMENT:

NOTE: This guideline only applies to member contracts that include comparative effectiveness language, and when the relative cost of the in-scope, non-oncology medication administered at a hospital-affiliated outpatient facility is greater when compared to an alternative site of care as described in the section below entitled Comparative Effectiveness Analysis.

Administration of an injectable non-oncology medication in a hospital-affiliated outpatient setting **meets the definition of medical necessity** for a medication in **Table 1** when the drug-specific medical coverage guideline (MCG) criteria are met, and **ONE** of the following is met:

1. The member is receiving the first dose of the medication authorized by Florida Blue under the Site of Care guideline*
2. The member is reinitiating therapy after more than 6 months following discontinuation*
3. The member does not have access to the medication from **ALL** of the following entities: home infusion agency†, professional office setting, or non-hospital-affiliated outpatient facility
4. The professional office or non-hospital-affiliated outpatient facility is greater than 45 miles from the member's home, and further away than the hospital-affiliated outpatient facility, **AND** the member is unable to receive the medication by a home infusion agency†

5. The member has a history of a severe adverse event (e.g., anaphylaxis) that is unable to be prevented with standard premedication – *documentation must be submitted*
6. The member has a higher risk of an adverse reaction due to a co-morbid condition (e.g., renal dysfunction, cardiopulmonary disease, physical/cognitive impairment) - *documentation of co-morbid condition, potential adverse reaction, and clinical rationale all must be submitted*
7. When a home infusion agency is the ONLY available alternative site of care - the member has unstable venous access – *documentation must be submitted*
8. The member has received a bone marrow transplant (BMT) or chimeric antigen receptor (CAR) T-cell therapy in the prior 6 months and requires enhanced medical supervision/monitoring at a specialized facility – *documentation of the procedure/treatment must be submitted*
9. The member is less than 18 years of age

Approval duration: see the associated drug-specific medical coverage guideline (MCG) for the duration of approval - maximum approval duration of 1 year (*60-day temporary authorization to permit transition to an alternate site of care; for Fasenra, Reblozyl, and Vyvgart/Vyvgart Hytrulo a 90-day and for Entyvio a 120-day temporary authorization, respectively, is permitted)

†Home infusion agency is unable to provide care for the member or the home environment is considered unsafe by the home infusion agency or provider

Table 1: Non-Oncology Medications for Site of Care Review

ACTEMRA (intravenous use only)
ADAKEVO
ALDURAZYME
ALYGLO
ARALAST NP
ASCENIV
AVSOLA
AVTOZMA (intravenous use only)
BENLYSTA
BIVIGAM
BKEMV
BRIUMVI
CARIMUNE NF
CEREZYME
CIMZIA
CINQAIR
COSENTYX (intravenous use only)
CRYSVITA
ELAPRASE
ELELYSO
ELFABRIO
ENTYVIO (intravenous use only)
EPYSQLI
EVKEEZA
EXDENSUR
FABRAZYME
FASENRA
FLEBOGAMMA DIF
GAMMAGARD LIQUID (intravenous use only)
GAMMAGARD S/D
GAMMAKED (intravenous use only)
GAMMAPLEX

GAMUNEX-C (intravenous use only)
GLASSIA
ILARIS
ILUMYA
IMMUNE GLOBULIN
INFLECTRA
KANUMA
KYSTEXXA
LAMZEDE
LUMIZYME
MEPSEVII
NAGLAZYME
NEXVIAZYME
NUCALA
OCREVUS
OCREVUS ZUNOVO
OCTAGAM
ONPATTRO
ORENCIA (intravenous use only)
OXLUMO
PANZYGA
PRIVIGEN
PROLASTIN-C
RADICAVA
REBLOZYL
REMICADE
RENFLEXIS
RYSTIGGO
SAPHNELO
SIGNIFOR LAR
SIMPONI ARIA
SOLIRIS
TEPEZZA
TEZSPIRE
TOFIDENCE (intravenous use only)
TYENNE (intravenous use only)
TYRUKO
TYSABRI
ULTOMIRIS
UPLIZNA
VIMIZIM
VPRIV
VYEPTI
VYVGART
VYVGART HYTRULO
XOLAIR
YIMMUGO
ZEMAIRA

Comparative Effectiveness Analysis: Only applies to member contracts that contain a comparative effectiveness analysis within the definition of Medical Necessity. It has been shown that certain provider-administered, non-oncology medications administered at a member's home, professional office setting, or non-hospital-affiliated outpatient infusion facility are equally safe and have at least similar quality

outcomes compared to a hospital-affiliated outpatient infusion facility. Analysis under this comparative effectiveness section should be applied, solely for coverage and payment purposes. Initially, this analysis should determine if: 1.) There is an alternate service available that produces the same or similar outcomes and/or 2.) The same service as requested or performed can be rendered at a different location of service. If there is no alternative service that produces the same or similar outcomes nor is there a different location at which the services could be rendered, then no further comparative effectiveness analysis need be completed, and the service will be deemed to have met the definition of medical necessity. If, however, there are alternative services that produce the same or similar outcomes and/or there is a different location of service at which the services can be rendered, then a comparative effectiveness analysis must be conducted to determine if: a.) The same service rendered at a different location, or b.) An alternate service(s) is/are less costly. If the answer is yes, then the requested service does satisfy the requirements of this comparative effectiveness analysis.

BILLING/CODING INFORMATION:

The following codes may be used to describe:

HCPCS Coding

J0129	Injection, abatacept, 10 mg
J0180	Injection, agalsidase beta, 1 mg
J0217	Injection, velmanase alfa-tycv, 1 mg
J0219	Injection, avalglucosidase alfa-ngpt, 4 mg
J0221	Injection, alglucosidase alfa, (Lumizyme), 10 mg
J0222	Injection, patisiran, 0.1 mg
J0224	Injection, lumasiran, 0.5 mg
J0256	Injection, alpha 1 proteinase inhibitor (human), not otherwise specified, 10 mg
J0257	Injection, alpha 1 proteinase inhibitor (human), (Glassia), 10 mg
J0490	Injection, belimumab, 10 mg
J0491	Injection, anifrolumab-fnia, 1 mg
J0517	Injection, benralizumab, 1 mg
J0584	Injection, burosumab-twza 1 mg
J0638	Injection, canakinumab, 1 mg
J0717	Injection, certolizumab pegol, 1 mg
J0791	Injection, crizanlizumab-tmca, 5 mg
J0896	Injection, luspatercept-aamt, 0.25 mg
J1300	Injection, eculizumab, 10 mg
J1301	Injection, edaravone, 1 mg
J1303	Injection, ravulizumab-cwvz, 10 mg
J1305	Injection, evinacumab-dgnb, 5mg
J1322	Injection, elosulfase alfa, 1 mg
J1458	Injection, galsulfase, 1 mg
J1459	Injection, immune globulin (Privigen), intravenous, non-lyophilized (e.g. liquid), 500 mg
J1552	Injection, immune globulin (Alyglo), 500 mg
J1553	Injection, immune globulin (Yimmugo), 100 mg
J1556	Injection, immune globulin (Bivigam), 500 mg
J1557	Injection, immune globulin, (Gammaplex), intravenous, non-lyophilized (e.g. liquid), 500 mg
J1561	Injection, immune globulin, (Gamunex-C/Gammaked), non-lyophilized (e.g. liquid), 500 mg

J1566	Injection, immune globulin, intravenous, lyophilized (e.g. powder), not otherwise specified, 500 mg (Carimune NF, Panglobulin NF, and Gammagard S/D)
J1568	Injection, immune globulin, (Octagam), intravenous, non-lyophilized (e.g. liquid), 500 mg
J1569	Injection, immune globulin, (Gammagard liquid), non-lyophilized, (e.g. liquid), 500 mg
J1572	Injection, immune globulin, (Flebogamma/Flebogamma DIF), intravenous, non-lyophilized (e.g. liquid), 500 mg
J1599	Injection, immune globulin, intravenous, non-lyophilized (e.g. liquid), not otherwise specified, 500 mg
J1602	Injection, golimumab, 1 mg, for intravenous use
J1743	Injection, idursulfase, 1 mg
J1745	Injection, infliximab, 10 mg
J1786	Injection, imiglucerase, 10 units
J1823	Injection, inebilizumab-cdon, 1 mg
J1931	Injection, laronidase, 0.1 mg
J2182	Injection, mepolizumab, 1 mg
J2323	Injection, natalizumab, 1 mg
J2329	Injection, ublituximab-xiiy, 1 mg
J2350	Injection, ocrelizumab, 1 mg
J2351	Injection, ocrelizumab, 1 mg and hyaluronidase-ocsq
J2356	Injection, tezepelumab-ekko, 1 mg
J2357	Injection, omalizumab, 5 mg
J2361	Injection, depemokimab-ulaa, 1 mg
J2502	Injection, pasireotide long acting, 1 mg
J2507	Injection, pegloticase, 1 mg
J2508	Injection, pegunigalsidase alfa-iwxj, 1 mg
J2786	Injection, reslizumab, 1 mg
J2840	Injection, sebelipase alfa, 1 mg
J3032	Injection, eptinezumab-jjmr, 1 mg
J3060	Injection, taliglucerase alfa, 10 units
J3241	Injection, teprotumumab-trbw, 10 mg
J3245	Injection, tildrakizumab, 1 mg
J3247	Injection, secukinumab, intravenous, 1 mg
J3262	Injection, tocilizumab, 1 mg
J3397	Injection, vestronidase alfa-vjbk, 1 mg
J3380	Injection, vedolizumab, 1 mg
J3385	Injection, velaglucerase alfa, 100 units
J3590	Unclassified biologics [for Exdensur only]
J9332	Injection, efgartigimod alfa-fcab, 2 mg
J9333	Injection, rozanolixizumab-noli, 1 mg
J9334	Injection, efgartigimod alfa, 2 mg and hyaluronidase-qvfc
Q5103	Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg
Q5104	Injection, infliximab-abda, biosimilar, (Renflexis). 10 mg
Q5121	Injection, infliximab-axxq, biosimilar, (Avsola), 10 mg
Q5133	Injection, tocilizumab-bavi (Tofidence), biosimilar, 1 mg
Q5134	Injection, natalizumab-sztn (Tyruko), biosimilar, 1 mg
Q5135	Injection, tocilizumab-aazg (Tyenne), biosimilar, 1 mg
Q5151	Injection, eculizumab-aagh (Epysqli), biosimilar, 2 mg

Q5152	Injection, eculizumab-aeeb (Bkemv), biosimilar, 2 mg
Q5156	Injection, tocilizumab-anoh (Avtozma), biosimilar, 1 mg

REIMBURSEMENT INFORMATION:

Refer to section entitled POSITION STATEMENT.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): FEP is excluded from this guideline; follow FEP guidelines.

State Account Organization (SAO): SAO is excluded from this guideline; follow SAO guidelines.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) related to Site of Care were found at the time of the last guideline review date. Medicare Advantage is excluded from this guideline.

DEFINITIONS:

Place of Service Code(s)	Place of Service Name	Place of Service Description
19	Off Campus-Outpatient Hospital	A portion of an off-campus hospital provider-based department which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization. (Effective January 1, 2016)
22	On Campus-Outpatient Hospital	A portion of a hospital's main campus which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization. (Description change effective January 1, 2016)

RELATED GUIDELINES:

Abatacept (Orencia), 09-J0000-67

Agalsidase Beta (Fabrazyme) IV, 09-J2000-59

Alpha1-Proteinase Inhibitors (Human), 09-J0000-49

Belimumab (Benlysta) IV, 09-J1000-35

Benralizumab (Fasenra) Injection, 09-J2000-92

Burosumab (Crysvita), 09-J2000-99

Canakinumab (Ilaris) Injection, 09-J2000-03

Certolizumab Pegol (Cimzia), 09-J0000-77

Crizanlizumab-tmca (Adakveo), 09-J3000-56

Drugs and Biologics without a Medical Coverage Guideline, 09-J0000-68

Eculizumab (Soliris) IV, 09-J1000-17

Edaravone (Radicava) IV, 09-J2000-82

Efgartigimod alfa-fcab (Vyvgart, Vyvgart Hytrulo) Injection, 09-J4000-18

Elosulfase alfa (Vimizim) Injection, 09-J2000-13

Enzyme Replacement Therapy for Pompe Disease, 09-J4000-06

Eptinezumab-jjmr (Vyepti), 09-J3000-68

Evinacumab-dgnb (Evkeeza) Infusion, 09-J3000-99

Golimumab (Simponi, Simponi Aria), 09-J1000-11

Immune Globulin Therapy, 09-J0000-06

Inebilizumab (Uplizna) Injection, 09-J3000-73

Infliximab Products, 09-J0000-39

Intravenous Enzyme Replacement Therapy for Gaucher Disease, 09-J0000-41

Lumasiran (Oxlumo) Injection, 09-J3000-91

Lupus, 09-J5000-51

Luspatercept-aamt (Reblozyl), 09-J3000-61

Mepolizumab (Nucala) Injection, 09-J2000-54

Natalizumab (Tysabri), 09-J0000-73

Ocrelizumab (Ocrevus, Ocrevus Zunovo) Infusion, 09-J2000-78

Omalizumab (Xolair), 09-J0000-44

Pasireotide (Signifor Signifor LAR) Injection, 09-J1000-94

Pegloticase (Krystexxa) Infusion, 09-J3000-29

Pegunigalsidase (Elfabrio) IV Infusion, 09-J4000-56

Ravulizumab (Ultomiris) IV, 09-J3000-26

Reslizumab (Cinqair) IV Infusion, 09-J2000-63

Rozanolixizumab-noli (Rystiggo) Injection, 09-J4000-55

Secukinumab (Cosentyx) Injection and Infusion, 09-J2000-30

Tezepelumab-ekko (Tezspire), 09-J4000-13

Tildrakizumab-asmn (Ilumya), 09-J3000-04

Tocilizumab Products (Actemra, Tofidence, and Tyenne), 09-J1000-21

Transthyretin Amyloidosis (ATTR), 09-J5000-50

Ublituximab-xiiy (Briumvi), 09-J4000-44

Velmanase alfa-tycv (Lamzede), 09-J4000-50

OTHER:

None

REFERENCES:

1. Broyles AD, Banerji A, Barmettler S, et al. Practical guidance for the evaluation and management of drug hypersensitivity: Specific drugs. J Allergy Clin Immunol Pract. 2020; 8(95):S16-S116.

2. Enzyme-replacement therapies for Lysosomal Storage Diseases. The Agency for Healthcare Research and Quality. 2013. Available at: https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/lysosomal-storage-diseases-therapies_technical-brief.pdf.
3. Guidelines for the site of care for IVIG. The American Academy of Allergy Asthma & Immunology. 2011. Available at: https://www.aaaai.org/practice-resources/practice-tools/ivig-toolkit.
4. National Home Infusion Association. About home and specialty infusion. Available at: https://www.nhia.org/about-infusion-therapy/.
5. Place of Service Code set. Centers for Medicare & Medicaid Services. 2016. Available at: https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set.html.
6. Riazi A, Porter B, Chataway J, et al. A tool to measure the attributes of receiving IV therapy in a home versus hospital setting: the Multiple Sclerosis Relapse management Scale (MSRMS). Health Qual Life Outcomes. 2011; 9:80.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 08/12/26.

GUIDELINE UPDATE INFORMATION:

11/11/19	New Medical Coverage Guideline.
01/15/20	Revision to guideline consisting of updating the position statement.
02/15/20	Revision: Updated HCPCS codes.
03/15/20	Revision to guideline consisting of updating the position statement and billing/coding based on the addition of Avsola (infliximab-axxq).
05/08/20	Revision to guideline consisting of updating the position statement and billing/coding based on the addition of Tepezza (teprotumumab).
06/01/21	Revision to guideline consisting of updating the billing/coding based on revised HCPCS codes.
01/01/22	Review and revision to guidelines consisting of updating the position statement and references.
06/15/22	Revision to guideline consisting of updating the position statement, billing/coding, and related guidelines based on the additions of Tezspire and Vyvgart.
07/01/22	Revision: HCPCS code updates for Tezspire and Vyvgart.
04/01/23	Revision to guideline consisting of updating the position statement, billing/coding, and related guidelines based on the addition of Briumvi.
07/15/23	Revision to guideline consisting of updating the position statement, billing/coding, and related guidelines based on the addition of Lamzede. New HCPCS code for Briumvi.
09/15/23	Revision to guideline consisting of updating the position statement, billing/coding, and related guidelines based on the additions of Elfabrio, Rystiggo, and Vyvgart Hytrulo.
01/01/24	Revision: HCPCS code updates for Elfabrio, Lamzede, Rystiggo, and Vyvgart Hytrulo.
07/01/24	Revision to guideline consisting of updating the position statement, billing/coding, and related guidelines based on the additions of Tofidence and Tyenne.
12/15/24	Revision to guideline consisting of updating the position statement, billing/coding, and related guidelines based on the addition of Ocrevus Zunovo.
01/01/25	Revision: HCPCS code update for Tyenne,
07/01/26	Revision to guideline consisting of updating the list of drugs in scope, and the geoaccess and unstable venous access exception criteria. MCG title changed to Site of Care Guideline for Select Non-Oncology Medications.
09/01/26	Added Program Exceptions section and Comparative Effectiveness Analysis section to clarify the members and lines of business in-scope of this guideline.