

09-J3000-39

Original Effective Date: 07/15/19

Reviewed: 11/09/22

Revised: 01/01/23

Subject: Step Therapy Requirements for Medicare Outpatient (Part B) 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 MEDICARE ADVANTAGE LINES OF BUSINESS ONLY.

DESCRIPTION:

The Centers for Medicare and Medicaid Services (CMS) has authorized Medicare Advantage (MA) plans to use step therapy for Part B drugs as part of a patient-centered care coordination program. Step therapy may include a Part B drug before Part B drug and Part D drug before Part B drug. Existing drug therapy must be grandfathered in; therefore, the step therapy program applies to new starts only. Medicare Advantage plans are permitted to require trial/failure of drugs supported only by off-label indication if well supported in accordance with CMS-approved compendia. Beneficiaries must also have the opportunity to participate in drug management care coordination activities, including at minimum: interactive medication review and associated consultations for enrollees to discuss all current medications and perform medication reconciliation and implementation medication adherence strategies to help enrollees with their medication regimen.

POSITION STATEMENT:

Step therapy will be required, and **the definition of medical necessity met**, for the medications listed in the Table below provided **ALL** of the following are met ("1" to "4"):

1. The requested product meets the definition of a Medicare outpatient (Part B) drug; **AND**
2. The proposed use of the requested product has been determined to be a medically accepted indication; **AND**
3. The proposed use of the preferred alternative agent has been determined to be a medically accepted indication; **AND**
4. The dose, frequency, and duration of use may not exceed the safety and efficacy data supporting the medically accepted indication

Anti-Inflammatory Agents

| Preferred Product(s) | | Non-preferred Product | |
|--------------------------|-------|-----------------------|-------|
| Injectable betamethasone | J0702 | Acthar HP | J0800 |

| | | | |
|--|---|----------|-------|
| Injectable methylprednisolone Injectable dexamethasone Injectable hydrocortisone Injectable triamcinolone | J1020 J1030 J1040 J1100 J1720 J2920 J2930 J3301 J3303 | | |
| Injectable triamcinolone (Kenalog) | J3301 | Zilretta | J3304 |

Cancer and Supportive Therapy

| Preferred Product(s) | | Non-preferred Product(s) | |
|---|---|--|----------------------------------|
| granisetron ondansetron | J1626 J2405 | Aloxi (Step therapy will only apply when in combination with LEC and MinEC) | J2469 |
| granisetron ondansetron Aloxi | J1626 J2405 J2469 | Sustol (for all indications) | J1627 |
| leucovorin | J0640 | Fusilev Khapzory | J0641 J0642 |
| Mvasi Zirabev | Q5107 Q5118 | Avastin (for oncology diagnosis only) | J9035 |
| Ontruzant Herzuma Ogivri Trazimera Kanjinti | Q5112 Q5113 Q5114 Q5116 Q5117 | Herceptin Herceptin Hylecta | J9355 J9356 |
| Truxima Ruxience | Q5115 Q5119 | Rituxan Rituxan Hycela (for oncology diagnosis only) Riabni | J9312 J9310 J9311 Q5123 |
| Belrapzo Bendeka | J3301 J9034 | Treanda | J9033 |
| Zoledronic acid | J3489 | Xgeva | J0897 |

Colony Stimulating Factors

| Preferred Product(s) | Non-preferred Product |
|----------------------|-----------------------|
|----------------------|-----------------------|

| | | | |
|--|----------------------------------|----------|-------|
| Fulphila Udenyca Nyvepria Ziextenzo | Q5108 Q5111 Q5122 Q5120 | Neulasta | J2505 |
| Granix Zarxio Nivestym | J1447 Q5101 Q5110 | Neupogen | J1442 |

Complement Inhibitors

| Preferred Product(s) | | Indication | Non-preferred Product | |
|---|----------------|--|-----------------------|-------|
| Ultomiris Vyvgart | J1303 J9332 | Myasthenia gravis (gMG) | Soliris | J1300 |
| Empaveli Ultomiris | C9399 J1303 | Paroxysmal Nocturnal Hemoglobinuria (PNH) | | |
| Ultomiris | J1303 | Hemolytic uremic syndrome, atypical (aHUS) | | |
| Enspryng Uplinza | C9399 J1823 | Neuromyelitis optica spectrum disorder (NMOSD) | | |
| *ST does <u>not</u> apply for other orphan indications - only medical necessity criteria for Soliris as per CMS guidance | | *Other orphan indications: dermatomyositis, shiga-toxin producing E. coli HUS, idiopathic membranous glomerular nephropathy, prevention of delayed graft rejection in renal transplant | | |

Erythropoiesis Stimulating Agents

| Preferred Product(s) | | Non-preferred Product | |
|----------------------|-------|--|-------|
| Retacrit | Q5106 | *Procrit/Epogen (*Step therapy does not apply until shortage is resolved) | J0885 |

Ophthalmic Agents

| Preferred Product(s) | | Non-preferred Product | |
|----------------------|-------|---|---|
| Bevacizumab | J3590 | Alymsys Beovu Byooviz Cimerli Eylea | C9142 J0179 Q5124 C9399 J0178 |

| | | | |
|--|--|--|----------------------------------|
| | | Lucentis Macugen Vabysmo Visudyne | J2778 J2503 J2777 J3396 |
|--|--|--|----------------------------------|

Viscosupplements

| Preferred Product(s) | | Non-preferred Product | |
|----------------------------------|-------|--|--|
| Synvisc/Synvisc One Orthovisc | J7325 | Durolane Euflexxa Gel-One Gelsyn-3 Genvisc-850 Hyalgen Hymovis Monovisc Supartz Supartz FX Triluron Visco-3 | J7318 J7323 J7326 J7328 J7320 J7321 J7322 J7327 J7321 J7321 J7332 J7321 |

Note: Step therapy may only be applied to new prescriptions or administrations of Part B drugs for enrollees that are not actively receiving the affected medication.

LEC = low emetogenic chemotherapy, MinEC = minimal emetogenic chemotherapy

Exceptions

- Medicare Advantage Products: Medical necessity is determined using any applicable NCD or LCD and then Step therapy Requirements for Medicare Outpatient (Part B) Medications (09-J3000-39).
- Enrollees must be able to request an exception from the plan's step therapy requirement in order to access a Part B covered drug. The ability to request such an exception is consistent with current Part D rules involving exceptions related to the application of utilization management tools, such as step therapy requirements. 42 CFR § 423.578(b)
- CMS considers plan decisions involving requests for exceptions to be pre-service organization determinations because they involve an MA plan's refusal to provide or pay for services that the enrollee believes should be furnished or arranged by the MA plan. 42 CFR § 422.566(b)(3)
- As a result, exception requests are subject to applicable adjudication timeframes and notice requirements in 42 CFR §§ 422.568 and 422.572. Organization determination timeframes require that MA plans make determinations as expeditiously as the enrollee's health condition requires, but no later than 72 hours (24 hours for expedited requests) after the date the organization receives the request.

Approval duration: 1 year

BILLING/CODING INFORMATION:

The following codes may be used to describe:

HCPCS Coding

| | |
|-------|--|
| C9142 | Injection, bevacizumab-maly, biosimilar, (alymys), 10 mg |
| J0178 | Injection, aflibercept, 1 mg |
| J0179 | Injection, brolocizumab-dbl, 1 mg |
| J0640 | Injection, leucovorin calcium, per 50 mg |
| J0641 | Injection, levoleucovorin calcium, 0.5 mg |
| J0642 | Injection, levoleucovorin, 0.5mg |
| J0702 | Injection, betamethasone acetate 3 mg and betamethasone sodium phosphate 3 mg |
| J0800 | Injection, corticotropin, up to 40 units |
| J0885 | Injection, epoetin alfa, (for non-ESRD use), 1000 units |
| J0897 | Injection, denosumab, 1 mg |
| J1020 | Injection, methylprednisolone acetate, 20 mg |
| J1030 | Injection, methylprednisolone acetate, 40 mg |
| J1040 | Injection, methylprednisolone acetate, 80 mg |
| J1100 | Injection, dexamethasone sodium phosphate, 1 mg |
| J1300 | Injection, eculizumab, 10 mg |
| J1303 | Injection, ravulizumab-cwvz, 10 mg |
| J1447 | Injection, tbo-filgrastim, 1 microgram |
| J1626 | Injection, granisetron hydrochloride, 100 mcg |
| J1627 | Injection, granisetron, extended release, 0.1 mg |
| J1720 | Injection, hydrocortisone sodium succinate, up to 100 mg |
| J1823 | Injection, inebilizumab-cdon, 1 mg |
| J2405 | Injection, ondansetron hydrochloride, per 1 mg |
| J2469 | Injection, palonosetron HCl, 25 mcg |
| J2503 | Injection, pegaptanib sodium, 0.3 mg |
| J2505 | Injection, pegfilgrastim, 6 mg |
| J2777 | Injection, faricimab-svoa, 0.1 mg |
| J2778 | Injection, ranibizumab, 0.1 mg |
| J2920 | Injection, methylprednisolone sodium succinate, up to 40 mg |
| J3301 | Injection, triamcinolone acetonide, Not Otherwise Specified, per 10 mg |
| J3304 | Injection, triamcinolone acetonide, preservative-free, extended release, microsphere formulation, 1 mg |
| J3396 | Injection, verteporfin, 0.1 mg |
| J3489 | Injection, zoledronic acid, 1 mg |
| J7318 | Hyaluronan or derivative, durolane, for intra-articular injection, 1 mg |
| J7320 | Hyaluronan or derivative, Genvisc 850, for intra-articular injection, 1 mg |
| J7321 | Hyaluronan or derivative, hyalgan, supartz or visco-3, for intra-articular injection |
| J7322 | Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg |
| J7323 | Hyaluronan or derivative, Euflexxa, for intra-articular injection, per dose (20 mg/2 mL) |
| J7325 | Hyaluronan or derivative, Synvisc or Synvisc-One, for intra-articular injection, 1 mg |
| J7326 | Hyaluronan or derivative, Gel-One, for intra-articular injection |

| | |
|-------|---|
| J7327 | Hyaluronan or derivative, Monovisc, for intra-articular injection, per dose |
| J7328 | Hyaluronan or derivative, GELSYN-3, for intra-articular injection, 0.1 mg |
| J7332 | Hyaluronan or derivative, triluron, for intra-articular injection, 1 mg |
| J9033 | Injection, bendamustine HCL, 1 mg |
| J9034 | Injection, bendamustine HCl (Bendeka), 1 mg |
| J9035 | Injection, bevacizumab, 10mg |
| J9311 | Injection, rituximab, 10mg and hyaluronidase |
| J9312 | Injection, rituximab, 10mg |
| J9332 | Injection, efgartigimod alfa-fcab, 2mg |
| J9355 | Injection, trastuzumab 10 mg |
| J9356 | Injection, trastuzumab, 10 mg and hyaluronidase-oysk |
| Q5101 | Injection, filgrastim-sndz, biosimilar, (Zarxio), 1 microgram |
| Q5106 | Injection, epoetin alfa-epbx, biosimilar, (retacrit) (for non-esrd use), 1000 units |
| Q5107 | Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg |
| Q5108 | Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg |
| Q5110 | Injection, filgrastim-aafi, biosimilar, (Nivestym), 1 microgram |
| Q5111 | Injection, Pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg |
| Q5112 | Injection, trastuzumab-dttb, biosimilar, (Ontruzant), 10 mg |
| Q5113 | Injection, trastuzumab-pkrb, biosimilar, (Herzuma), 10 mg |
| Q5114 | Injection, Trastuzumab-dkst, biosimilar, (Ogivri), 10 mg |
| Q5115 | Injection, rituximab-abbs, biosimilar, (Truxima), 10 mg |
| Q5116 | Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg |
| Q5117 | Injection, trastuzumab-anns, biosimilar, (kanjinti), 10 mg |
| Q5118 | Injection, bevacizumab-bvzr, biosimilar, (Zirabev), 10 mg |
| Q5119 | Injection, rituximab-pvvr, biosimilar, (ruxience), 10 mg |
| Q5120 | Injection, pegfilgrastim-bmez, biosimilar, (ziextenzo), 0.5 mg |
| Q5122 | Injection, pegfilgrastim-apgf, biosimilar, (nyvepria), 0.5 mg |
| Q5123 | Injection, rituximab-arrx, biosimilar, (riabni), 10 mg |
| Q5124 | Injection, ranibizumab-nuna, biosimilar, (byooviz), 0.1 mg |

ICD-10 Diagnosis Codes That Support Medical Necessity

| Acthar | |
|---------------|--|
| A15.0–A15.9 | Respiratory tuberculosis |
| A17.0 | Tuberculous meningitis |
| B02.39 | Other herpes zoster eye disease |
| B75 | Trichinellosis |
| C81.00–C96.9 | Malignant neoplasm of lymphatic and hematopoietic tissue |
| D59.00–D59.9 | Acquired hemolytic anemias |
| D61.01 | Constitutional (pure)red cel aplasia |
| D61.89 | Other aplastic anemias and other bone marrow failure syndromes |
| D69.59 | Other secondary thrombocytopenia |
| D86.0–D86.9 | Sarcoidosis |

| | |
|-----------------|---|
| E06.1 | Subacute thyroiditis |
| E83.52 | Hypercalcemia |
| G12.21 | Amyotrophic lateral sclerosis |
| G35 | Multiple sclerosis |
| H10.001–H10.44 | Conjunctivitis |
| H16.001–H16.299 | Keratitis |
| H20.00–H20.9 | Iridocyclitis |
| H30.001–H30.93 | Chorioretinal inflammations |
| H44.11–H44.19 | Other endophthalmitis |
| H44.131–H44.139 | Sympathetic uveitis |
| H46.00–H46.9 | Optic neuritis |
| I100–I02.9 | Acute rheumatic fever |
| J30.01–J30.9 | Allergic rhinitis |
| J45.20–J45.998 | Asthma |
| J63.2 | Berylliosis |
| J68.0 | Bronchitis and pneumonitis due to chemicals, gases, fumes and vapors |
| J69.0–J69.8 | Pneumonitis due to inhalation of food or vomit |
| J82 | Pulmonary eosinophilia |
| K29.60–K29.61 | Other gastritis |
| K50.00–K50.919 | Chron's disease |
| K51.00–K51.919 | Ulcerative colitis |
| K52.21–K52.29 | Allergic and dietary gastroenteritis and colitis |
| L10.0–L10.9 | Pemphigus |
| L13.0 | Dermatitis herpetiformis |
| L21.8–L21.9 | Seborrheic dermatosis |
| L24.0–L24.9 | Irritant contact dermatitis |
| L27.0–L27.9 | Dermatitis due to substances taken internally |
| L40.0–L40.9 | Psoriasis |
| L50.0–L50.9 | Urticaria |
| L51.1 | Stevens-Johnson syndrome |
| M05.00 –M14.89 | Inflammatory polyarthropathies |
| M10.00 –M10.09 | Idiopathic gout |
| M15.0–M19.93 | Osteoarthritis |
| M32.0–M32.9 | Systemic lupus erythematosus |
| M45.0–M45.9 | Ankylosing spondylitis |
| M75.00–M77.9 | Shoulder lesions |
| N04.0–N04.9 | Nephrotic syndrome |
| T50.905 | Adverse effect of unspecified drugs, medicaments, and biological substances |
| T78.3 | Angioneurotic edema |
| T78.40 | Allergy, unspecified |
| T80.51–T80.59 | Anaphylactic reaction due to serum |
| T80.61–T80.69 | Other serum reaction |

| Aloxi | |
|--------------|---|
| R11.0 | Nausea |
| R11.10 | Vomiting, unspecified |
| R11.11 | Vomiting without nausea |
| R11.12 | Projectile vomiting |
| R11.2 | Nausea with vomiting, unspecified |
| T45.1X5A | Adverse effect of antineoplastic and immunosuppressive drugs, initial encounter |
| T45.1X5D | Adverse effect of antineoplastic and immunosuppressive drugs, subsequent encounter |
| T45.1X5S | Adverse effect of antineoplastic and immunosuppressive drugs, sequela |
| T45.95XA | Adverse effect of unspecified primarily systemic and hematological agent, initial encounter |
| T50.905A | Adverse effect of unspecified drugs, medicaments and biological substances, initial encounter |
| T50.905S | Adverse effect of unspecified drugs, medicaments and biological substances, sequela |
| T66.xxxS | Radiation sickness, unspecified, sequela |
| Z51.11 | Encounter for antineoplastic chemotherapy |
| Z51.12 | Encounter for antineoplastic chemotherapy |

| Bendamustine HCL | |
|-------------------------|---|
| B20 | Human immunodeficiency virus (HIV) disease |
| C81.00–C81.09 | Nodular lymphocyte predominant Hodgkin lymphoma |
| C81.10–C81.19 | Nodular sclerosis classical Hodgkin lymphoma |
| C81.20–C81.29 | Mixed cellularity classical Hodgkin lymphoma |
| C81.30–C81.39 | Lymphocyte depleted classical Hodgkin lymphoma |
| C81.40–C81.49 | Lymphocyte-rich classical Hodgkin lymphoma |
| C81.70–C81.79 | Other classical Hodgkin lymphoma |
| C81.90–C81.99 | Hodgkin lymphoma, unspecified |
| C82.00–C82.09 | Follicular lymphoma grade I |
| C82.10–C82.19 | Follicular lymphoma grade II |
| C82.20–C82.29 | Follicular lymphoma grade III, unspecified |
| C82.30–C82.39 | Follicular lymphoma grade IIIa |
| C82.40–C82.49 | Follicular lymphoma grade IIIb |
| C82.50–C82.59 | Diffuse follicle center lymphoma |
| C82.60–C82.69 | Cutaneous follicle center lymphoma |
| C82.80–C82.89 | Other types of follicular lymphoma |
| C82.90–C82.99 | Follicular lymphoma, unspecified |
| C83.00–C83.09 | Small B-cell lymphoma |
| C83.10–C83.19 | Mantle cell lymphoma |
| C83.30–C83.39 | Diffuse large B-cell lymphoma |

| | |
|---------------|---|
| C83.50–C83.59 | Lymphoblastic (diffuse) lymphoma |
| C83.80–C83.89 | Other non-follicular lymphoma |
| C83.90–C83.99 | Non-follicular (diffuse) lymphoma, unspecified |
| C84.00–C84.09 | Mycosis fungoides |
| C84.40–C84.49 | Peripheral T-cell lymphoma, not classified |
| C84.60–C84.69 | Anaplastic large cell lymphoma, ALK-positive |
| C84.70–C84.79 | Anaplastic large cell lymphoma, ALK-negative |
| C84.90–C84.99 | Mature T/NK-cell lymphomas, unspecified |
| C84.Z0–C84.Z9 | Other mature T/NK-cell lymphomas |
| C85.20–C85.29 | Mediastinal (thymic) large B-cell lymphoma |
| C85.80–C85.89 | Other specified types of non-Hodgkin lymphoma |
| C86.1 | Hepatosplenic T-cell lymphoma |
| C86.2 | Enteropathy-type (intestinal) T-cell lymphoma |
| C86.5 | Angioimmunoblastic T-cell lymphoma |
| C86.6 | Primary cutaneous CD30-positive T-cell proliferations |
| C88.0 | Waldenström macroglobulinemia |
| C88.4 | Extranodal marginal zone B-cell lymphoma of mucosa-associated lymphoid tissue [MALT-lymphoma] |
| C88.8 | Other malignant immunoproliferative diseases |
| C90.00 | Multiple myeloma not having achieved remission |
| C90.02 | Multiple myeloma in relapse |
| C90.10 | Plasma cell leukemia not having achieved remission |
| C90.12 | Plasma cell leukemia in relapse |
| C90.20 | Extramedullary plasmacytoma not having achieved remission |
| C90.22 | Extramedullary plasmacytoma in relapse |
| C90.30 | Solitary plasmacytoma not having achieved remission |
| C90.32 | Solitary plasmacytoma in relapse |
| C91.10 | Chronic lymphocytic leukemia of B-cell type not having achieved remission |
| C91.12 | Chronic lymphocytic leukemia of B-cell type in relapse |
| C91.50 | Adult T-cell lymphoma/leukemia (HTLV-1-associated), not having achieved remission |
| C91.52 | Adult T-cell lymphoma/leukemia (HTLV-1-associated), in relapse |
| D47.Z1 | Post-transplant lymphoproliferative disorder (PTLD) |

| | |
|-------------------------------|---------------------------------------|
| Fusilev | |
| C15.3–C15.5 C15.8 C15.9 | Malignant neoplasm of esophagus |
| C16.0–C16.9 | Malignant neoplasm of stomach |
| C17.0–C17.3 C17.8 C17.9 | Malignant neoplasm of small intestine |

| | |
|------------------------------|---|
| C18.0–C18.9 | Malignant neoplasm of the colon |
| C19 | Malignant neoplasm of rectosigmoid junction |
| C20 | Malignant neoplasm of rectum |
| C21.0 - C21.8 | Malignant neoplasm of overlapping sites of rectum, anus and anal canal |
| C25.0 - C25.4 C25.7–C25.9 | Malignant neoplasm of pancreas |
| C37 | Malignant neoplasm of thymus |
| C40.00–C40.02 | Malignant neoplasm of scapula and long bones of upper limb |
| C40.10–C40.12 | Malignant neoplasm of short bones of upper limb |
| C40.20–C40.22 | Malignant neoplasm of long bones of lower limb |
| C40.30–C40.32 | Malignant neoplasm of short bones of lower limb |
| C40.80–C40.82 | Malignant neoplasm of overlapping sites of bone and articular cartilage of limb |
| C40.90–C40.92 | Malignant neoplasm of unspecified bones and articular cartilage of limb |
| C41.0–C41.4 C41.9 | Malignant neoplasm of bone and articular cartilage of other and unspecified sites |
| C48.1–C48.8 | Malignant neoplasm of retroperitoneum and peritoneum |
| C53.0–C53.9 | Malignant neoplasm of cervix uteri |
| C56.1–C56.9 | Malignant neoplasm of ovary |
| C57.00–C57.9 | Malignant neoplasm of other and unspecified female genital organs |
| C67.0–C67.9 | Malignant neoplasm of bladder |
| C78.00–C78.02 | Secondary malignant neoplasm of lung |
| C78.1 | Secondary malignant neoplasm of mediastinum |
| C78.2 | Secondary malignant neoplasm of pleura |
| C78.30, C78.39 | Secondary malignant neoplasm of other and unspecified respiratory organs |
| C78.4 | Secondary malignant neoplasm of small intestine |
| C78.5 | Secondary malignant neoplasm of large intestine and rectum |
| C78.6 | Secondary malignant neoplasm of retroperitoneum and peritoneum |
| C78.7 | Secondary malignant neoplasm of liver and intrahepatic bile duct |
| C78.80, C78.89 | Secondary malignant neoplasm of other and unspecified digestive organs |
| C79.31, C79.32 | Secondary malignant neoplasm of brain and cerebral meninges |
| C79.40, C79.49 | Secondary malignant neoplasm of other and unspecified parts of nervous system |
| C79.89, C79.9 | Secondary malignant neoplasm of other specified and unspecified site |
| C80.0 | Disseminated malignant neoplasm, unspecified |
| C80.1 | Malignant (primary) neoplasm, unspecified |
| C83.00–C83.09 | Small cell b-cell lymphoma |
| C83.10–C83.19 | Mantle cell lymphoma |
| C83.30–C83.39 | Diffuse large b-cell lymphoma |
| C83.50–C83.59 | Lymphoblastic (diffuse) lymphoma |
| C83.70–C83.79 | Burkitt lymphoma |
| C83.80–C83.89 | Other non-follicular lymphoma |
| C83.90–C83.99 | Non-follicular (diffuse) lymphoma, unspecified |
| C84.40–C84.49 | Mature T/NK-cell lymphomas |

| | |
|---------------------------------|---|
| C84.60–C84.69 | Anaplastic large cell lymphoma, alk-positive |
| C84.70–C84.79 | Anaplastic large cell lymphoma, alk-negative |
| C84.Z0–C84.Z9 | Other mature T/NK-cell lymphomas |
| C84.90–C84.99 | Mature T/NK-cell lymphomas, unspecified |
| C85.80–C85.89 | Other specified types of non-hodgkin lymphoma |
| C86.0–C86.6 | Other specified types of T/NK-cell lymphoma |
| C91.00–C91.02 | Acute lymphoblastic leukemia [all] |
| C91.50–C91.52 | Adult T-cell lymphoma/leukemia |
| C91.Z0 | Other lymphoid leukemia not having achieved remission |
| C91.Z2 | Other lymphoid leukemia, in relapse |
| D15.0 | Benign neoplasm of thymus |
| D37.1–D37.9 | Neoplasm of uncertain behavior of oral cavity and digestive organs |
| T36.8X1A, t36.8X1D, T36.8X1S | Poisoning by other systemic antibiotics, accidental (unintentional) |
| T36.8X2A, T36.8X2D, T36.8X2S | Poisoning by other systemic antibiotics, intentional self-harm |
| T36.8X3A, T36.8X3D, T36.8X3S | Poisoning by other systemic antibiotics, assault |
| T36.8X4A, T36.8X4D, 36.8X4S | Poisoning by other systemic antibiotics, undetermined |
| T37.0X1A, T37.0X1D, T37.0X1S | Poisoning by sulfonamides, accidental (unintentional) |
| T37.0X2A, T37.0X2D, T37.0X2S | Poisoning by sulfonamides, intentional self-harm |
| T37.0X3A, T37.0X3D, T37.0X3S | Poisoning by sulfonamides, assault |
| T37.0X4A, T37.0X4D, T37.0X4S | Poisoning by sulfonamides, undetermined |
| T37.2X1A, T37.2X1D, T37.2X1S | Poisoning by antimalarials and drugs acting on other blood protozoa, accidental (unintentional) |
| T37.2X2A, T37.2X2D T37.2X2S | Poisoning by antimalarials and drugs acting on other blood protozoa, intentional self-harm |
| T37.2X3A, T37.2X3D, T37.2X3S | Poisoning by antimalarials and drugs acting on other blood protozoa, assault |
| T37.2X4A, T37.2X4D, T37.2X4S | Poisoning by antimalarials and drugs acting on other blood protozoa, undetermined |
| T39.4X1A, T39.4X1D, T39.4X1S | Poisoning by antirheumatics, not elsewhere classified, accidental (unintentional) |
| T39.4X2A, T39.4X2D, T39.4X2S | Poisoning by antirheumatics, not elsewhere classified, intentional self-harm |
| T39.4X3A, T39.4X3D, T39.4X3S | Poisoning by antirheumatics, not elsewhere classified, assault |

| | |
|---------------------------------|---|
| T39.4X4A, T39.4X4D, T39.4X4S | Poisoning by antirheumatics, not elsewhere classified, undetermined |
| T45.1X1A, T45.1X1D, T45.1X1S | Poisoning by antineoplastic and immunosuppressive drugs, accidental (unintentional) |
| T45.1X2A, T45.1X2D, T45.1X2S | Poisoning by antineoplastic and immunosuppressive drugs, intentional self-harm |
| T45.1X3A, T45.1X3D, T45.1X3S | Poisoning by antineoplastic and immunosuppressive drugs, assault |
| T45.1X4A, T45.1X4D, T45.1X4S | Poisoning by antineoplastic and immunosuppressive drugs, undetermined |
| T45.1X5A, T45.1X5D, T45.1X5S | Adverse effect of antineoplastic and immunosuppressive drugs |

| | |
|---|---|
| Herceptin | |
| C50.011–C50.019 C50.111–C50.119 C50.211–C50.219 C50.311–C50.319 C50.411–C50.419 C50.511–C50.519 C50.611–C50.619 C50.811–C50.819 C50.911–C50.919 | Malignant neoplasm of the female breast |
| C50.021–C50.029 C50.121–C50.129 C50.221–C50.229 C50.321–C50.329 C50.421–C50.429 C50.521–C50.529 C50.621–C50.629 C50.821–C50.829 C50.921–C50.929 | Malignant neoplasm of the male breast |
| C16.0–C16.9 | Malignant neoplasm of the stomach |

| | |
|-------------------|--|
| Macugen | |
| E08.311 | Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy with macular edema |
| E08.3211–E08.3219 | Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema |
| E08.3311–E08.3319 | Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema |

| | |
|-------------------|--|
| E08.3411–E08.3419 | Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema |
| E08.3511–E08.3519 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema |
| E09.311 | Drug or chemical induced diabetes mellitus with unspecified diabetic retinopathy with macular edema |
| E09.3211–E09.3219 | Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema |
| E09.3311–E09.3319 | Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema |
| E09.3411–E09.3419 | Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema |
| E09.3511–E09.3519 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema |
| E10.311 | Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema |
| E10.3211–E10.3219 | Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema |
| E10.3311–E10.3319 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema |
| E10.3411–E10.3419 | Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema |
| E10.3511–E10.3519 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema |
| E11.311 | Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema |
| E11.3211–E11.3219 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema |
| E11.3311–E11.3319 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema |
| E11.3411–E11.3419 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema |
| E11.3511–E11.3519 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema |
| E13.311 | Other specified diabetes mellitus with unspecified diabetic retinopathy with macular edema |
| E13.3211–E13.3219 | Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema |
| E13.3311–E13.3319 | Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema |
| E13.3411–E13.3419 | Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema |

| | |
|-------------------|--|
| E13.3511–E13.3519 | Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema |
| H35.3210–H35.3293 | Exudative age-related macular degeneration |

| Rituxan | |
|----------------|---|
| C82.00–C82.99 | Follicular lymphoma, Grades I-IIIb, diffuse follicle center lymphoma, cutaneous follicle center lymphoma, other and unspecified |
| C83.80–C83.89 | Other non-follicular lymphoma, lymph nodes of specific sites |
| C85.10–C85.19 | Unspecified B-cell lymphoma |
| C85.90–C85.99 | Non-Hodgkin's lymphoma, unspecified |
| C91.10 | Chronic lymphocytic leukemia of B-cell type not having achieved remission |
| C91.12 | Chronic lymphocytic leukemia of B-cell type in relapse |

| Soliris | |
|----------------|---|
| D59.31 | Infection-associated hemolytic-uremic syndrome |
| D59.32 | Hereditary hemolytic-uremic syndrome |
| D59.39 | Other hemolytic-uremic syndrome |
| D59.5 | Paroxysmal nocturnal hemoglobinuria [Marchiafava-Micheli] |
| G36.0 | Neuromyelitis optica [Devic] |
| G70.00 | Myasthenia gravis without (acute) exacerbation |
| G70.01 | Myasthenia gravis with (acute) exacerbation |
| N00.6 | Acute nephritic syndrome with dense deposit disease |
| N01.6 | Rapidly progressive nephritic syndrome with dense deposit disease |
| N02.6 | Recurrent and persistent hematuria with dense deposit disease |
| N03.6 | Chronic nephritic syndrome with dense deposit disease |
| N04.6 | Nephrotic syndrome with dense deposit disease |
| N07.6 | Hereditary nephropathy, not elsewhere classified with dense deposit disease |
| T86.19 | Other complication of kidney transplant |

| Viscosupplements | |
|-------------------------|--|
| M17.0 | Bilateral primary osteoarthritis of knee |
| M17.11 | Unilateral primary osteoarthritis, right knee |
| M17.12 | Unilateral primary osteoarthritis, left knee |
| M17.2 | Bilateral post-traumatic osteoarthritis of knee |
| M17.31 | Unilateral post-traumatic osteoarthritis, right knee |
| M17.32 | Unilateral post-traumatic osteoarthritis, left knee |
| M17.4 | Other bilateral secondary osteoarthritis of knee |
| M17.5 | Other unilateral secondary osteoarthritis of knee |
| M17.9 | Osteoarthritis of knee, unspecified |
| M19.011 | Primary osteoarthritis, right shoulder |
| M19.012 | Primary osteoarthritis, left shoulder |
| M19.111 | Post-traumatic osteoarthritis, right shoulder |
| M19.112 | Post-traumatic osteoarthritis, left shoulder |
| M19.211 | Secondary osteoarthritis, right shoulder |
| M19.212 | Secondary osteoarthritis, left shoulder |
| M75.41 | Impingement syndrome of right shoulder |

| | |
|--------|---------------------------------------|
| M75.42 | Impingement syndrome of left shoulder |
|--------|---------------------------------------|

| Visudyne | |
|-------------------|--|
| B39.4 | Histoplasmosis capsulate, unspecified |
| B39.5 | Histoplasmosis duboisii |
| B39.9 | Histoplasmosis, unspecified |
| H32 | Chorioretinal disorders in diseases classified elsewhere |
| H35.3210–H35.3293 | Exudative age-related macular degeneration |
| H44.2A1 | Degenerative myopia with choroidal neovascularization, right eye |
| H44.2A2 | Degenerative myopia with choroidal neovascularization, left eye |
| H44.2A3 | Degenerative myopia with choroidal neovascularization, bilateral eye |
| H44.2A9 | Degenerative myopia with choroidal neovascularization, unspecified eye |

| Xgeva | |
|-----------------|---|
| C33 | C33 Malignant neoplasm of trachea |
| C34.00–C34.02 | C34.00–C34.02 Malignant neoplasm of unspecified main bronchus |
| C34.10–C34.12 | Malignant neoplasm of upper lobe, unspecified bronchus or lung |
| C34.2 | Malignant neoplasm of middle lobe, bronchus or lung |
| C34.30–C34.32 | Malignant neoplasm of lower lobe, unspecified bronchus or lung |
| C34.80–C34.82 | Malignant neoplasm of overlapping sites of unspecified bronchus and lung |
| C34.90–C34.92 | Malignant neoplasm of unspecified part of unspecified bronchus or lung |
| C41.0–C41.9 | Malignant neoplasm of bone and articular cartilage of other and unspecified sites |
| C50.011–C50.929 | Malignant neoplasm of breast |
| C61 | Malignant neoplasm of prostate |
| C64.1–C64.9 | Malignant neoplasm of unspecified kidney, except renal pelvis |
| C65.1–C65.9 | Malignant neoplasm of unspecified renal pelvis |
| C73 | Malignant neoplasm of thyroid gland |
| C79.51–C79.52 | Secondary malignant neoplasm of bone and bone marrow |
| C90.00–C90.02 | Multiple myeloma |
| D48.0 | Neoplasm of uncertain behavior of bone and articular cartilage |
| E83.52 | Hypercalcemia |

| Zilretta | |
|-----------------|--|
| M17.0 | Bilateral primary osteoarthritis of knee |
| M17.11 | Unilateral primary osteoarthritis, right knee |
| M17.12 | Unilateral primary osteoarthritis, left knee |
| M17.2 | Bilateral post-traumatic osteoarthritis of knee |
| M17.31 | Unilateral post-traumatic osteoarthritis, right knee |
| M17.32 | Unilateral post-traumatic osteoarthritis, left knee |
| M17,4 | Other bilateral secondary osteoarthritis of knee |
| M17.5 | Other unilateral secondary osteoarthritis of knee |

REIMBURSEMENT INFORMATION:

Refer to section entitled [POSITION STATEMENT](#).

RELATED GUIDELINES:

[Erythropoiesis Stimulating Agents, 09-J0000-31](#)

[Granulocyte Colony Stimulating Factors, 09-J0000-62](#)

[H.P. Acthar Gel \(Repository corticotropin\), 09-J1000-15](#)

[Levoleucovorin \(Fusilev and Khapzory\) IV, 09-J2000-31](#)

[Palonosetron Hydrochloride \(Aloxi\), 09-J0000-87](#)

[Vascular Endothelial Growth Factor Inhibitors for Ocular Neovascularization, 09-J1000-78](#)

[Bendamustine HCL\(Treanda\), 09-J2000-40](#)

[Denosumab, \(Xgeva\), 09-J1000-25](#)

[Verteprofin, \(Visudyne\), 09-J1000-72](#)

REFERENCES:

1. Centers for Medicare and Medicaid Services, Health Plan Management System (HPMS), MA_Step_Therapy_HPMS_Memo_8_7_18; available at <http://www.cms.gov> - last checked August 31, 2018 and found under Medicare > Health Plans > Health Plans - General Information > Downloads.
2. Centers for Medicare and Medicaid Services, Medicare Benefit Policy Manual, CMS Pub. 100-02, Chapter 15, Sec. 50 (Rev. 241, Feb. 2, 2018); available at <http://www.cms.gov> - last checked August 31, 2018 and found under Medicare > Regulations and Guidance > Manuals > Internet-Only Manuals (IOMs).
3. Local Coverage Determination (LCD). Centers for Medicare & Medicare Services. <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>.
4. National Coverage Determination (NCD). Centers for Medicare & Medicare Services. <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>.
5. U.S. Food & Drug Administration. FDA Approved Drug Products. <https://www.accessdata.fda.gov/scripts/cder/daf/>.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 07/13/22.

GUIDELINE UPDATE INFORMATION:

| | |
|----------|---|
| 07/15/19 | New Medical Coverage Guideline. |
| 01/01/21 | Review and revision to guideline; consisting of updating position statement, HCPCS coding and ICD-10 codes. |

| | |
|----------|--|
| 06/15/22 | Review and revision to guideline; consisting of updating position statement. |
| 08/01/22 | Review and revision to guideline. |
| 11/09/22 | Review and revision to guideline; updated drug tables format. |
| 01/01/23 | Review and revision to guideline, including addition of new ST programs. |