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Subject: Step Therapy Requirements for Medicare Outpatient (Part B) Medications

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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) Alymsys Vegzelma Avzivi	J9035 C9142 Q5126 Q5129 C9399 J3590
Ontruzant Herzuma Ogivri Trazimera Kanjinti	Q5112 Q5113 Q5114 Q5116 Q5117	Herceptin Herceptin Hylecta	J9355 J9356
Truxima Ruxience	Q5115 Q5119	Rituxan	J9312 J9310

		Rituxan Hycela (for oncology diagnosis only) Riabni	J9311 Q5123
Belrapzo Bendeka	J3301 J9034	Treanda	J9033
Zoledronic acid	J3489	Xgeva	J0897

Cardiovascular/Cholesterol Lowering Agents

Preferred Product(s)		Non-preferred Product	
Repatha*	J3590	Leqvio	J1306
Praluent*	C9399		

*Covered under Part D benefit (pre-authorization may apply)

Colony Stimulating Factors

Preferred Product(s)		Non-preferred Product	
Fulphila	Q5108	Neulasta	J2506
Udenyca	Q5111	Fylnetra	Q5130
Nyvepria	Q5122	Rolvedon	J1449
Ziextenzo	Q5120	Stimufend	Q5127
		Ryzneuta	J3590
Granix	J1447	Neupogen	J1442
Zarxio	Q5101	Releuko	Q5125
Nivestym	Q5110	Leukine	J2820

Complement Inhibitors

Preferred Product(s)		Indication	Non-preferred Product	
Ultomiris	J1303	Myasthenia gravis (gMG)	Soliris	J1300
Vyvgart	J9332			
Vyvgart Hytrulo	C9399			
Rystiggo	J3590			
Empaveli	C9399	Paroxysmal Nocturnal Hemoglobinuria (PNH)		
Ultomiris	J1303			

Ultomiris	J1303	Hemolytic uremic syndrome, atypical (aHUS)		
Enspryng Uplizna	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) Aranesp Mircera	J0885 J0881 J0887

Ophthalmic Agents

Preferred Product(s)		Non-preferred Product	
Bevacizumab	J3490 C9257	Beovu Byooviz Cimerli Eylea Eylea HD Lucentis Macugen Susvimo Vabysmo Visudyne	J0179 Q5124 C9399 Q5128 J0178 C9399, J3590 J2778 J2503 J2779 J2777 J3396

Viscosupplements

Preferred Product(s)	Non-preferred Product
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Synvisc/Synvisc One Orthovisc	J7325	Durolane	J7318
	J7324	Euflexxa	J7323
		Gel-One	J7326
		Gelsyn-3	J7328
		Genvisc-850	J7320
		Hyalgan	J7321
		Hymovis	J7322
		Monovisc	J7327
		Supartz	J7321
		Supartz FX	J7321
		Triluron	J7332
		Trivisc	J7329
		Visco-3	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, (alymsys), 10 mg
C9257	Injection, bevacizumab, 0.25 mg
J0178	Injection, aflibercept, 1 mg
J0179	Injection, brolocizumab-dblI, 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
J0881	Injection, darbepoetin alfa, 1 microgram
J0885	Injection, epoetin alfa, (for non-ESRD use), 1000 units
J0887	Injection, epoetin beta, 1 microgram
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
J1306	Injection, inclisiran, 1 mg
J1447	Injection, tbo-filgrastim, 1 microgram
J1449	Injection, eflapegrastim-xnst, 0.1 mg
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
J2506	Injection, pegfilgrastim, 6 mg
J2777	Injection, faricimab-svoa, 0.1 mg
J2778	Injection, ranibizumab, 0.1 mg
J2779	Injection, ranibizumab, via intravitreal implant (susvimo), 0.1 mg
J2820	Injection, sargramostim (GM-CSF), 50 mcg
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)
J7324	Hyaluronan or derivative, Orthovisc, for intra-articular injection, per dose (30 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, (udenyc), 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
Q5125	Injection, filgrastim-ayow, biosimilar, (releuko), 1 microgram
Q5126	Injection, bevacizumab-maly, biosimilar, (alymysys), 10 mg
Q5127	Injection, pegfilgrastim-fpgk (stimufend), biosimilar, 0.5 mg
Q5128	Injection, ranibizumab-eqrn (cimerli), biosimilar, 0.1 mg
Q5129	Injection, bevacizumab-adcd (vegzelma), biosimilar, 10 mg
Q5130	Injection, pegfilgrastim-pbbk (fynetra), biosimilar, 0.5 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
C84.20 – C84.29	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
C91.20	Other lymphoid leukemia not having achieved remission
C91.22	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	Malignant neoplasm of the male breast

C50.821 – C50.829 C50.921 – C50.929	
C16.0 – C16.9	Malignant neoplasm of the stomach

Leqvio	
E78.00	Pure hypercholesterolemia, unspecified
E78.01	Familial hypercholesterolemia
E78.2	Mixed hyperlipidemia
E78.4	Other hyperlipidemia
E78.49	Other hyperlipidemia, familial combined hyperlipidemia
E78.5	Hyperlipidemia, unspecified
E78.9	Disorder of lipoprotein metabolism, unspecified
I20.2	Refractory angina pectoris
I20.8	Other forms of angina pectoris
I20.9	Angina pectoris, unspecified
I21.01 – I21.A9	Acute myocardial infarction
I22.0 – I22.9	Subsequent ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction
I23.7	Postinfarction angina
I24.0	Acute coronary thrombosis not resulting in myocardial infarction
I24.8	Other forms of acute ischemic heart disease
I25.10 – I25.9	Chronic ischemic heart disease
I63.00 – I63.9	Cerebral infarction
I65.01 – I65.9	Occlusion and stenosis of precerebral arteries, not resulting in cerebral infarction
I66.01 – I66.9	Occlusion and stenosis of cerebral arteries, not resulting in cerebral infarction
I67.2	Cerebral atherosclerosis
I67.81	Acute cerebrovascular insufficiency
I67.82	Cerebral ischemia
I67.89	Other cerebrovascular disease
I67.9	Cerebrovascular disease, unspecified
I68.8	Other cerebrovascular disorders in diseases classified elsewhere
I70.0 – I70.92	Atherosclerosis
I73.89	Other specified peripheral vascular diseases
I73.9	Peripheral vascular disease, unspecified
I74.01 – I74.9	Arterial embolism and thrombosis
I75.011 – I75.89	Atheroembolism
Z95.1	Presence of aortocoronary bypass graft
Z95.5	Presence of coronary angioplasty implant and graft
Z95.820	Peripheral vascular angioplasty status with implants and grafts
Z98.61	Coronary angioplasty status
Z98.62	Peripheral vascular angioplasty status

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](#)

[Eculizumab \(Soliris®\), 09-J1000-17](#)

[Inclisiran \(Leqvio®\), 09-J4000-21](#)

REFERENCES:

- 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 11/08/23.

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.
05/15/23	Revision to guidelines, consisting of the addition of non-preferred drugs for ST programs: Alymsys, Vegzelma [oncology]; Fylnetra, Rolvedon, Stimufend [pegylated filgrastim-colony stimulating factor]; Releuko, Leukine [filgrastim/ sargramostim - colony stimulating factor]; Aranesp, Mircera [epoetin]; Susvimo [ophthalmic-VEGF].
01/01/24	Review and revision to guideline, including addition of new ST programs.
03/15/24	Review and revision to guidelines, consisting of addition of non-preferred drugs for ST programs: Avzivi [oncology]; Ryzneuta [colony stimulating factors].