Maximum Dosage and Frequency (for Indiana Only)

Policy Number: CSIND0034.03
Effective Date: January 1, 2022

Instructions for Use

Table of Contents Page

Related Policies

- Complement Inhibitors (Soliris® & Ultomiris®) (for Indiana Only)
- Denosumab (Prolia® & Xgeva®) (for Indiana Only)
- Infliximab (Avsola™, Inflectra®, Remicade®, & Renflexis®) (for Indiana Only)
- Oncology Medication Clinical Coverage (for Indiana Only)
- Onpattro® (Patisiran) (for Indiana Only)
- Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors (for Indiana Only)
- Rituximab (Riabni™, Rituxan®, Ruxience®, & Truxima®) (for Indiana Only)
- White Blood Cell Colony Stimulating Factors (for Indiana Only)
- Xolair® (Omalizumab) (for Indiana Only)

Application

This Medical Benefit Drug Policy only applies to the state of Indiana.

Coverage Rationale

This policy provides information about the maximum dosage per administration and dosing frequency for certain medications administered by a medical professional. Most medications have a maximum dosage and frequency based upon body surface area or patient weight or a set maximal dosage and frequency independent of patient body size.

Drug Products

- Abatacept (Orencia®)
- Aflibercept (Eylea®)
- Bevacizumab (Avastin®)
- Bevacizumab-awwb (Mvasi™)
- Bevacizumab-bvzr (Zirabev™)
- Brolucizumab-dbll (Beovu®)
- Certolizumab pegol (Cimzia®)
- Denosumab (Prolia® & Xgeva®)
- Eculizumab (Soliris®)
- Emicizumab-kxwh (Hemlibra®)
- Golimumab (Simponi Aria®)
- Infliximab (Remicade®)
- Infliximab-axxq (Avsola™)
- Infliximab-dyyb (Inflectra®)
- Infliximab-abda (Renflexis®)
- Nivolumab (Opdivo®)
- Omalizumab (Xolair®)
- Patisiran (Onpattro®)
- Pegaptanib sodium (Macugen®)
- Pegfilgrastim (Neulasta®)
- Pegfilgrastim-apgf (Nyvepria™)
- Pegfilgrastim-cbqv (Udenyca™)
- Pegfilgrastim-jmdb (Fulphila™)
- Pegfilgrastim-bmez (Ziextenzo™)
- Ranibizumab (Lucentis®)
- Ravulizumab-cwvz (Ultomiris®)
- Rituximab (Rituxan®)
- Rituximab-pvvr (Ruxience®)
- Rituximab-abbs (Truxima®)
- Rituximab and hyaluronidase (Rituxan Hycela®)
- Testosterone cypionate (Depo-Testosterone®)
- Testosterone enanthate
- Testosterone pellets (Testopel®)

- Testosterone undecanoate (Aveed®)
- Tildrakizumab-asmn (Ilumya™)
- Tocilizumab (Actemra®)
- Trastuzumab (Herceptin®)
- Trastuzumab-anns (Kanjinti™)
- Trastuzumab-dkst (Ogivri™)
- Trastuzumab-dttb (Ontruzant™)
- Trastuzumab-pkrb (Herzuma®)
- Trastuzumab-qyyp (Trazimera™)
- Ustekinumab (Stelara®)
- Vedolizumab (Entyvio®)
- Zoledronic acid (zoledronic acid, Reclast® and Zometa®)

The use of medications included in this policy when given within the maximum dosage and/or frequency based upon body surface area or patient weight or a set of maximal dosage and/or frequency independent of patient body size are proven when used according to labeled indications or when otherwise supported by published clinical evidence.

The medications included in this policy when given beyond maximum dosages and/or frequency based upon body surface area or patient weight or a set maximal dosage independent of patient body size are not supported by package labeling or published clinical evidence and are unproven.

This policy creates an upper dose limit based on the clinical evidence and the 95th percentile for adult body weight (128 kg) and body surface area (2.59 meters^2) in the U.S. (adult male, 30 to 39 years, Fryar, 2016). In some cases, the maximum allowed units and/or vials may exceed the upper-level limit as defined within this policy due to an individual patient body weight > 128 kg or body surface area > 2.59 meters^2.

Maximum Allowed Quantities by HCPCS Units

Medication Name		Diagnosis	Maximum Dosage per Administration	HCPCS Code	Maximum Allowed
Brand	Generic				
Actemra	tocilizumab		800 mg	J3262	800 HCPCS units (1 mg per unit)
Avastin	bevacizumab		15 mg/kg	J9035	192 HCPCS units (10 mg per unit)
Mvasi	bevacizumab-awwb		15 mg/kg	Q5107	192 HCPCS units (10 mg per unit)
Zirabev	bevacizumab-bvzr		15 mg/kg	Q5118	192 HCPCS units (10 mg per unit)
Aveed	testosterone undecanoate		750 mg	J3145	750 HCPCS units (1 mg per unit)
Cimzia	certolizumab pegol		400 mg	J0717	400 HCPCS units (1 mg per unit)
NA	testosterone enanthate		400 mg	J3121	400 HCPCS units (1 mg per unit)
Depo-Testosterone	testosterone cypionate		400 mg	J1071	400 HCPCS units (1 mg per unit)
Entyvio	vedolizumab		300 mg	J3380	300 HCPCS units (1 mg per unit)
Hemlibra	emicizumab-kxwh		6 mg/kg	J7170	1,536 HCPCS units (0.5 mg per unit)
Herceptin	trastuzumab		8 mg/kg	J9355	103 HCPCS units (10 mg per unit)
Herzuma	trastuzumab-pkrb		8 mg/kg	Q5113	103 HCPCS units (10 mg per unit)
Kanjinti	trastuzumab-anns		8 mg/kg	Q5117	103 HCPCS units (10 mg per unit)
Ogivri	trastuzumab-dkst		8 mg/kg	Q5114	103 HCPCS units (10 mg per unit)

Medication Name		Diagnosis	Maximum Dosage per Administration	HCPCS Code	Maximum Allowed
Brand	Generic				
Ontruzant	trastuzumab-dttb		8 mg/kg	Q5112	103 HCPCS units (10 mg per unit)
Trazimera	trastuzumab-qyyp		8 mg/kg	Q5116	103 HCPCS units (10 mg per unit)
Ilumya	tildrakizumab-asmn		100 mg	J3245	100 HCPCS units (1 mg per unit)
Neulasta	pegfilgrastim		6 mg	J2506	12 HCPCS unit (0.5 mg per unit)
Nyvepria	pegfilgrastim-apgf		6 mg	Q5122	12 HCPCS units (0.5 mg per unit)
Fulphila	pegfilgrastim-jmdb		6 mg	Q5108	12 HCPCS units (0.5 mg per unit)
Udenyca	pegfilgrastim-cbqv		6 mg	Q5111	12 HCPCS units (0.5 mg per unit)
Ziextenzo	pegfilgrastim-bmez		6 mg	Q5120	12 HCPCS units (0.5 mg per unit)
Opdivo	nivolumab		480 mg	J9299	480 HCPCS units (1 mg per unit)
Orencia	Abatacept		1,000 mg	J0129	100 HCPCS units (10 mg per unit)
Reclast	zoledronic acid		5 mg	J3489	5 HCPCS units (1 mg per unit)
Zometa	zoledronic acid		4 mg	J3489	5 HCPCS units (1 mg per unit)
zoledronic acid	zoledronic acid		5 mg	J3489	5 HCPCS units (1 mg per unit)
			4 mg	J3489	5 HCPCS units (1 mg per unit)
Remicade	infliximab		10 mg/kg	J1745	128 HCPCS units (10 mg per unit)
Renflexis	infliximab-abda		10 mg/kg	Q5104	128 HCPCS units (10 mg per unit)
Inflectra	infliximab-dyyb		10 mg/kg	Q5103	128 HCPCS units (10 mg per unit)
Avsola	infliximab-axxq		10 mg/kg	Q5121	128 HCPCS units (10 mg per unit)
Onpattro	patisiran		30 mg	J0222	300 HCPCS units (0.1 mg per unit)
Prolia	denosumab	Osteoporosis	60 mg	J0897	60 HCPCS units (1 mg per unit)
Xgeva	denosumab	Oncology	120 mg	J0897	120 HCPCS units (1 mg per unit)
Rituxan	rituximab		1,225 mg	J9312	123 HCPCS units (10 mg per unit)

Medication Name		Diagnosis	Maximum Dosage per Administration	HCPCS Code	Maximum Allowed
Brand	Generic				
Truxima	rituximab-abbs		1,225 mg	Q5115	123 HCPCS units (10 mg per unit)
Ruxience	rituximab-pvvr		1,225 mg	Q5119	123 HCPCS units (10 mg per unit)
Rituxan Hycela	rituximab and hyaluronidase		1,600 mg	J9311	160 HCPCS units (10 mg per unit)
Simponi Aria	golimumab		2 mg/kg	J1602	300 HCPCS units (1 mg per unit)
Soliris	eculizumab	PNH	900 mg	J1300	90 HCPCS units (10 mg per unit)
		aHUS, MG, NMOSD	1,200 mg	J1300	120 HCPCS units (10 mg per unit)
Stelara	ustekinumab		90 mg	J3357	90 HCPCS units (1 mg per unit)
		Crohn's Disease	520 mg	J3358	520 HCPCS units (1 mg per unit)
Testopel	testosterone pellet		450 mg	S0189	6 HCPCS units (75 mg per unit)
Ultomiris	ravulizumab-cwvz		3,600 mg	J1303	360 HCPCS units (10 mg per unit)
Xolair	omalizumab	Asthma	375 mg	J2357	90 HCPCS units (5 mg per unit)
		Chronic Urticaria	300 mg	J2357	60 HCPCS units (5 mg per unit)
		Nasal Polyps	600 mg	J2357	120 HCPCS units (5 mg per unit)

Maximum Allowed Quantities for National Drug Code (NDC) Billing

The allowed quantities in this section are calculated based upon both the maximum dosage information supplied within this policy as well as the process by which NDC claims are billed. This list may not be inclusive of all available NDCs for each drug product and is subject to change. Absence of a specific NDC does not mean that it is not subject to the following maximum allowed.

Medication Name		Diagnosis	How Supplied	National Drug Code	Maximum Allowed
Brand	Generic				
Actemra	Tocilizumab		20 mg/mL vial	50242-0135-01 50242-0136-01 50242-0137-01	40 mL
Avastin	bevacizumab		100 mg/4 mL vial	50242-0060-01 50242-0060-10	77 mL
			400 mg/16 mL vial	50242-0061-01 50242-0061-10	77 mL
Mvasi	bevacizumab-awwb		100 mg/4 mL vial	55513-0206-01	77 mL
			400 mg/16 mL vial	55513-0207-01	77 mL
Zirabev	bevacizumab-bvzr		100 mg/4 mL vial	00069-0315-01	77 mL
			400 mg/16 mL vial	00069-0342-01	77 mL

Medication Name		Diagnosis	How Supplied	National Drug Code	Maximum Allowed
Brand	Generic				
Aveed	testosterone undecanoate		750 mg/3 mL	67979-0511-43	3 mL
Cimzia	certolizumab pegol		2 x 200 mg kit	50474-0700-62	2 vials
			2 x 200 mg/ml prefilled syringe (PFS) kit	50474-0710-79	2 mL
			6 x 200 mg/ml PFS kit	50474-0710-81	2 mL
N/A	testosterone enanthate		200 mg/mL	00574-0821-05 00143-9750-01 00591-3221-26	2 mL
Depo-Testosterone	testosterone cypionate		200 mg/mL	00517-1830-01 52536-0625-10 52536-0625-01 64980-0467-99 69097-0802-32 69097-0802-37 00574-0827-01 76519-1210-00 00009-0086-01 00009-0417-01 00009-0520-01 69097-0536-37 69097-0537-31 69097-0537-37 50090-0330-00 00409-6562-02 00409-6562-22 00143-9659-01 62756-0017-40 62756-0016-40 00409-6557-01 00409-6562-01 00409-6562-20 76420-0650-01 00591-4128-79 00009-0085-10 00009-0086-10 00574-0827-10 00009-0520-10 00009-0347-02 62756-0015-40 00143-9726-01 00009-0417-02 63874-1061-01 00574-0820-01 00574-0820-10	2 mL
Entyvio	vedolizumab		300 mg vial	64764-0300-20	1 vial

Medication Name		Diagnosis	How Supplied	National Drug Code	Maximum Allowed
Brand	Generic				
Hemlibra	emicizumab-kxwh		30 mg/mL	50242-0920-01	768 mg
			105 mg/0.7 mL	50242-0922-01	768 mg
			150 mg/mL	50242-0923-01	768 mg
			60 mg/0.4 mL	50242-0921-01	768 mg
Herceptin	trastuzumab		150 mg vial	50242-0132-01 50242-0132-10	7 vials
Herzuma	trastuzumab-pkrb		420 mg vial	63459-0305-47 63459-0307-41	3 vials
			150 mg vial	63459-0303-43	3 vials
Kanjinti	trastuzumab-anns		420 mg vial	55513-0132-01	3 vials
			150 mg vial	55513-0141-01	3 vials
Ogivri	trastuzumab-dkst		420 mg vial	67457-0847-44 67457-0845-50	3 vials
			150 mg vial	67457-0991-15	3 vials
Ontruzant	trastuzumab-dttb		150 mg vial	00006-5033-02	3 vials
			420 mg vial	00006-5034-01 00006-5034-02	3 vials
Trazimera	trastuzumab-qyyp		420 mg vial	00069-0305-01 00069-0306-01	3 vials
Ilumya	tildrakizumab-asmn		100 mg/mL PFS	47335-0177-96 47335-0177-95 47335-0177-01 47335-0177-10	1 mL
Neulasta	pegfilgrastim		6 mg/0.6 mL PFS	55513-0190-01	0.6 mL
			6 mg/0.6 mL PFS with on-body Injector	55513-0192-01	0.6 mL
Nyvepria	pegfilgrastim-apgf		6 mg/0.6 mL PFS	00069-0324-01	0.6 mL
Fulphila	pegfilgrastim-jmdb		6 mg/0.6 mL PFS	67457-0833-06	0.6 mL
Udenyca	pegfilgrastim-cbqv		6 mg/0.6 mL PFS	70114-0101-01	0.6 mL
Ziextenzo	pegfilgrastim-bmez		6 mg/0.6 mL PFS	61314-0866-01	0.6 mL
Opdivo	nivolumab		100 mg/10 mL vial	00003-3774-12	40 mL
			240 mg/24 mL vial	00003-3734-13	48 mL
			40 mg/4 mL vial	00003-3772-11	8 mL
Onpattro	patisiran		10 mg/5 mL vial	71336-1000-01	15 mL
Orencia	abatacept		250 mg vial	00003-2187-10 00003-2187-13	4 vials
Remicade	infliximab		100 mg vial	57894-0030-01	13 vials
Avsola	infliximab-axxq		100 mg vial	55513-0670-01	13 vials
Renflexis	infliximab-abda		100 mg vial	00006-4305-01 00006-4305-02	13 vials
Inflectra	infliximab-dyyb		100 mg vial	00069-0809-01	13 vials
Rituxan	rituximab		100 mg/10 mL vial	50242-0051-10 50242-0051-21	40 mL

Medication Name		Diagnosis	How Supplied	National Drug Code	Maximum Allowed
Brand	Generic				
Rituxan	rituximab		500 mg/50 mL vial	50242-0053-06	130 mL
Ruxience	rituximab-pvvr		100 mg/10 mL vial	00069-0238-01	40 mL
			500 mg/50 mL vial	00069-0249-01	130 mL
Truxima	rituximab-abbs		100 mg/10 mL vial	63459-0103-10	40 mL
			500 mg/50 mL vial	63459-0104-50	130 mL
Rituxan Hycela	rituximab and hyaluronidase		1,400-23,400 mg/11.7 mL	50242-0108-01	1 vial
			1,600-26,800 mg/13.4 mL	50242-0109-01	1 vial
Simponi Aria	golimumab		50 mg/4 mL	57894-0350-01	24 mL
Soliris	eculizumab	PNH	300 mg/30 mL vial	25682-0001-01	90 mL
		aHUS, MG	300 mg/30 mL vial	25682-0001-01	120 mL
Stelara	ustekinumab		45 mg/0.5 mL PFS	57894-0060-03	0.5 mL
			45 mg/0.5 mL vial	57894-0060-02	0.5 mL
			90 mg/1 mL PFS	57894-0061-03	1 mL
		Crohn's Disease	130 mg/26 mL vial	57894-0054-27	104 mL
		Ulcerative colitis	130 mg/26 mL vial	57894-0054-27	104 mL
Testopel	testosterone pellet		75 mg pellet	66887-0004-01 66887-0004-10 66887-0004-20	6 pellets
Ultomiris	ravulizumab-cwvz		300 mg/30 mL vial	25682-0022-01	360 mL
Xolair	omalizumab	Asthma	150 mg vial	50242-0040-62	3 vials
			150 mg/1 mL PFS	50242-0215-01 50242-0215-86	2 mL
			75 mg/0.5 mL PFS	50242-0214-01	0.5 mL
		Chronic Urticaria	150 mg vial	50242-0040-86	2 vials
			150 mg/1 mL PFS	50242-0215-01 50242-0215-86	2 mL
		Nasal Polyps	150 mg vials	50242-0040-62	4 vials
			150 mg/1 mL PFS	50242-0215-01	4 mL
			75 mg/ 0.5 mL PFS	50242-0214-01	0.5 mL
Prolia	denosumab	Osteoporosis	60 mg/1 mL PFS	55513-0710-01	1 mL
Xgeva	denosumab	Oncology	120 mg/1.7 mL vial	55513-0730-01	1.7 mL
Reclast Zometa	zoledronic acid		4 mg/5 mL vial	00409-4215-01 00409-4215-05 16714-0815-01 16729-0242-31 23155-0170-31 25021-0801-66 43598-0330-11 51991-0065-98 54288-0100-01 55111-0685-07	5 mL

Medication Name		Diagnosis	How Supplied	National Drug Code	Maximum Allowed
Brand	Generic				
Reclast Zometa	zoledronic acid		4 mg/5 mL vial	55150-0266-05 63323-0961-98 67457-0390-54 68001-0366-22 68001-0366-25	5 mL
			4 mg/100 mL vial	70860-0210-51	100 mL
			4 mg/100 mL infusion	00409-4229-01 23155-0186-31 25021-0826-67 25021-0826-82	100 mL
Reclast Zometa	zoledronic acid		5 mg/100 mL vial	00078-0435-61 25021-0830-82 43598-0331-11 51991-0064-98 55111-0688-52 63323-0966-00 67457-0619-10	100 mL
			5 mg/100 mL infusion	00409-4228-01 25021-0830-82 67457-0794-10 70860-0802-82	100 mL

Maximum Allowed Frequencies

The allowed frequencies in this section are based upon the FDA approved prescribing information for the applicable medications. For indications covered by UnitedHealthcare without FDA approved dosing, the frequencies are derived from available clinical evidence. This list may not be inclusive of all medications listed and is subject to change.

Medication Name		Diagnosis	Maximum Frequency
Brand	Generic		
Actemra	tocilizumab	PJIA	Administered once every 4 weeks
		Rheumatoid Arthritis	Administered once every 4 weeks
		SJIA	Administered once every 2 weeks
Avastin	Bevacizumab	Choroidal neovascularization secondary to pathologic myopia, angioid streaks/pseudoxanthoma elasticum, or ocular histoplasmosis syndrome	The recommended dose is 1.25 mg (0.05 mL) near-monthly into affected eyes during the first 12 months, with fewer injections needed in subsequent years. Maximum of 12 doses per year per eye.
		Diabetic macular edema	
		Macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO)	
		Neovascular age-related macular degeneration	

Medication Name		Diagnosis	Maximum Frequency
Brand	Generic		
Avastin	bevacizumab	Neovascular glaucoma	The recommended dose is 1.25 mg (0.05 mL) near-monthly into affected eyes during the first 12 months, with fewer injections needed in subsequent years. Maximum of 12 doses per year per eye.
		Neovascularization of the iris (rubeosis iridis)	
		Proliferative diabetic retinopathy	
		Type I retinopathy of prematurity	
Aveed	testosterone undecanoate		The recommended dose is 750 mg initially, followed by 750 mg after 4 weeks, then 750 mg every 10 weeks thereafter
Beovu	brolucizumab	Neovascular age-related macular degeneration	The recommended dose is 6 mg (0.05 mL) into affected eye(s) once monthly (approximately every 25 to 31 days) for the first 3 doses, then 6 mg every 8 to 12 weeks thereafter. Maximum of 12 doses per year per eye.
Cimzia	certolizumab pegol	Crohn's Disease	Administered initially, and at weeks 2, 4, then every 4 weeks thereafter
		Ankylosing Spondylitis	Administered initially, and at weeks 2, 4, then every other/every 2 weeks thereafter
		Axial Spondyloarthritis	Administered initially, and at weeks 2, 4, then every other/every 2 weeks thereafter
		Plaque Psoriasis (BW ≤ 90 kg)	Administered initially, and at weeks 2, 4, then every other/every 2 weeks thereafter
		Psoriatic Arthritis	Administered initially, and at weeks 2, 4, then every other/every 2 weeks thereafter
		Rheumatoid Arthritis	Administered initially, and at weeks 2, 4, then every other/every 2 weeks thereafter
		Plaque Psoriasis (BW > 90 kg)	Administered every other week
N/A	testosterone enanthate		For replacement therapy, the suggested dosage is 50 mg to 400 mg every 2 to 4 weeks, not to exceed 400 mg per 14 days
Depo-testosterone	testosterone cypionate		For replacement in the hypogonadal male, the suggested dosage is 50 mg to 400 mg every 2 to 4 weeks, not to exceed 400 mg per 14 days
Entyvio	vedolizumab	Crohn's Disease	Administered at 0, 2, and 6 weeks, then every 8 weeks thereafter
		Ulcerative Colitis	Administered at 0, 2, and 6 weeks, then every 8 weeks thereafter
Eylea	Aflibercept	Diabetic macular edema	The recommended dose is 2 mg (0.05 mL) into affected eye(s) every 4 weeks (approximately every 28 days, monthly) for the first 20 weeks (5 months), then 2 mg every 8 weeks (2 months). Maximum of 12 doses per year per eye.
		Diabetic retinopathy	
		Macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO)	The recommended dose is 2 mg (0.05 mL) once every 4 weeks. Maximum of 12 doses per year per eye.

Medication Name		Diagnosis	Maximum Frequency
Brand	Generic		
Eylea	aflibercept	Neovascular age-related macular degeneration	The recommended dose is 2 mg (0.05 mL) into affected eye(s) every 4 weeks (approximately every 28 days, monthly) for the first 12 weeks (3 months), followed by 2 mg once every 8 weeks (2 months). Maximum of 12 doses per year per eye.
Fulphila	pegfilgrastim-jmdb	Oncology	Administered once every 2 weeks
Hemlibra	emicizumab-kxwh		3 mg/kg once weekly for the first 4 weeks, followed by maintenance dose of: • 1.5 mg/kg once every week; or • 3 mg/kg once every 2 weeks; or • 6 mg/kg once every 4 weeks
Ilumya	tildrakizumab-asmn	Plaque Psoriasis	Administered at weeks 0, 4, and every 12 weeks thereafter
Remicade Avsola Inflectra Renflexis	infliximab infliximab-axxq infliximab-dyyb infliximab-abda	Ankylosing Spondylitis	Administered at 0, 2, and 6 weeks, then every 6 weeks thereafter
		Crohn's Disease	Administered at 0, 2, and 6 weeks, then every 8 weeks thereafter
		Noninfectious uveitis	Administered at 0, 2, and 6 weeks, then every 8 weeks thereafter
		Plaque Psoriasis	Administered at 0, 2, and 6 weeks, then every 8 weeks thereafter
		Psoriatic Arthritis	Administered at 0, 2, and 6 weeks, then every 8 weeks thereafter
		Sarcoidosis	Administered at 0, 2, and 6 weeks, then every 8 weeks thereafter
		Ulcerative Colitis	Administered at 0, 2, and 6 weeks, then every 8 weeks thereafter
		Rheumatoid Arthritis	Administered at 0, 2, and 6 weeks, then every 8 weeks thereafter; Maintenance treatment may be increased to as often as every 4 weeks
Lucentis	Ranibizumab	Choroidal neovascularization secondary to pathologic myopia, angioid streaks/pseudoxanthoma elasticum, or ocular histoplasmosis syndrome	The recommended dose is 0.5 mg to affected eye(s) once a month (approximately every 28 days) for up to 3 months. May be retreated if necessary. Maximum of 12 doses per year per eye.
		Diabetic macular edema	The recommended dose is 0.3 mg to affected eye(s) once a month (approximately every 28 days). Maximum of 12 doses per year per eye.
		Diabetic retinopathy	
		Macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO)	The recommended dose is 0.5 mg to affected eye(s) once a month (approximately every 28 days). Maximum of 12 doses per year per eye.

Medication Name		Diagnosis	Maximum Frequency
Brand	Generic		
Lucentis	ranibizumab	Neovascular age-related macular degeneration	The recommended dose is 0.5 mg to affected eye(s) once a month (approximately every 28 days). Treatment may be reduced to 3 once monthly doses, followed by an average of 4 to 5 injections over the subsequent 9 months. Maximum of 12 doses per year per eye.
Macugen	pegaptanib	Diabetic macular edema	The recommended dose is 0.3 mg to affected eye(s) near-monthly during the first 12 months, with fewer injections needed in subsequent years. Maximum of 12 doses per year per eye.
		Neovascular age-related macular degeneration	The recommended dose is 0.3 mg to affected eye(s) once every 6 weeks. Maximum of 12 doses per year per eye.
Neulasta	pegfilgrastim	Oncology	Administered once every 2 weeks
Nyvepria	pegfilgrastim-apgf	Oncology	Administered once every 2 weeks
Onpattro	patisiran	Polyneuropathy from hATTR amyloidosis	Administered once every 3 weeks
Orencia	abatacept	JIA	Administered at 0, 2, and 4 weeks, then once every 4 weeks thereafter
		Rheumatoid Arthritis	Administered at 0, 2, and 4 weeks, then once every 4 weeks thereafter
		Psoriatic Arthritis	Administered at 0, 2, and 4 weeks, then once every 4 weeks thereafter
Prolia	denosumab	Osteoporosis	Administered once every 6 months
Simponi Aria	golimumab	Ankylosing Spondylitis	Administered at 0, 4, then every 8 weeks thereafter
		Juvenile Idiopathic Arthritis	Administered at 0, 4, then every 8 weeks thereafter
		Psoriatic Arthritis	Administered at 0, 4, then every 8 weeks thereafter
		Rheumatoid Arthritis	Administered at 0, 4, then every 8 weeks thereafter
Soliris	eculizumab	PNH, aHUS, MG, NMOSD	Administered once weekly for 5 doses, then every 2 weeks thereafter
Stelara	ustekinumab	Psoriasis	Administered subcutaneously - initially and 4 weeks later, then every 12 weeks thereafter
		Psoriatic arthritis	
		Crohn's Disease	Administered intravenously (IV) initially one time, then subcutaneously 8 weeks after the initial IV dose, then once every 8 weeks thereafter
Stelara	ustekinumab	Ulcerative colitis	Administered intravenously (IV) initially one time, then subcutaneously 8 weeks after the initial IV dose, then once every 8 weeks thereafter
Testopel	testosterone pellet		The dosage guideline for the testosterone pellets for replacement therapy in androgen-deficient males is 150 mg to 450 mg subcutaneously every 3 to 6 months. The usual dosage is as follows: implant two 75 mg pellets for each 25 mg testosterone propionate required weekly. Thus, when a patient requires injections of 75 mg per week, it is usually necessary to implant 450 mg (6 pellets). With injections of 50 mg per week, implantation of 300 mg (4 pellets) may suffice for approximately three months.

Medication Name		Diagnosis	Maximum Frequency
Brand	Generic		
Udenyca	pegfilgrastim-cbqv	Oncology	Administered once every 2 weeks
Ultomiris	ravulizumab-cwvz	PNH	Administered initially, week 2, then once every 8 weeks thereafter
		aHUS	Administered initially, week 2, then once every 4 or 8 weeks thereafter, depending on body weight
Xgeva	denosumab	Oncology	Administered once every 4 weeks
Xolair	omalizumab	Asthma	Administered once every 2 or 4 weeks, depending on body weight and IgE levels
		Chronic Urticaria	Administered once every 4 weeks
		Nasal Polyps	Administered once every 2 or 4 weeks, depending on body weight and IgE levels.
Ziextenzo	pegfilgrastim-bmez	Oncology	Administered once every 2 weeks

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
J0129	Injection, abatacept, 10 mg (Code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug self-administered)
J0222	Injection, patisiran, 0.1 mg
J0717	Injection, certolizumab pegol, 1 mg (Code may be used when drug administered under the direct supervision of a physician, not for use when drug is self-administered)
J0897	Injection, denosumab, 1 mg
J1071	Injection, testosterone cypionate, 1 mg
J1300	Injection, eculizumab, 10 mg
J1303	Injection, ravulizumab-cwvz, 10 mg
J1602	Injection, golimumab, 1 mg, for intravenous use
J1745	Injection, infliximab, excludes biosimilar, 10 mg
J2357	Injection, omalizumab, 5 mg
J2506	Injection, pegfilgrastim, excludes biosimilar, 0.5 mg
J3121	Injection, testosterone enanthate, 1 mg
J3145	Injection, testosterone undecanoate, 1 mg
J3245	Injection, tildrakizumab, 1 mg
J3262	Injection, tocilizumab, 1 mg
J3357	Ustekinumab, for subcutaneous injection, 1mg
J3358	Ustekinumab, for intravenous injection, 1 mg
J3380	Injection, vedolizumab, 1 mg
J3489	Injection, zoledronic acid, 1 mg
J7170	Injection, emicizumab-kxwh, 0.5 mg

HCPCS Code	Description
J9035	Injection, bevacizumab, 10 mg
J9299	Injection, nivolumab, 1 mg
J9311	Injection, rituximab 10 mg and hyaluronidase
J9312	Injection, rituximab, 10 mg
J9355	Injection, trastuzumab, excludes biosimilar, 10 mg
Q5103	Injection, Infliximab-dyyb, biosimilar, (Inflectra), 10 mg
Q5104	Injection, Infliximab-abda, biosimilar, (Renflexis), 10 mg
Q5107	Injection, bevacizumab-awwb, biosimilar, (Mvasi), 10 mg
Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (Fulphila), 0.5 mg
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
Q5121	Injection, infliximab-axxq, biosimilar, (Avsola), 10 mg
Q5122	Injection, pegfilgrastim-apgf, biosimilar, (Nyvepria), 0.5 mg
S0189	Testosterone pellet, 75 mg

National Drug Code	Description
50242-0135-01	Actemra 20 mg/mL vial
50242-0136-01	Actemra 200 mg/10 mL vial
50242-0137-01	Actemra 400 mg/20 mL vial
50242-0060-01	Avastin 100 mg/4 mL vial
50242-0060-10	
50242-0061-01	Avastin 400 mg/16 mL vial
50242-0061-10	
67979-0511-43	Aveed 750 mg/3 mL vial
55513-0670-01	Avsola 100 mg vial
50474-0700-62	Cimzia 2 x 200 mg kit
50474-0710-79	Cimzia 2 x 200 mg/ml prefilled syringe (PFS) kit
50474-0710-81	Cimzia 6 x 200 mg/ml PFS kit
00574-0821-05 00143-9750-01 00591-3221-26	Testosterone enanthate 200 mg/mL vial
00517-1830-01	Depo-Testosterone (testosterone cypionate) 200 mg/mL vial
52536-0625-10	
52536-0625-01	

National Drug Code	Description
64980-0467-99	Depo-Testosterone (testosterone cypionate) 200 mg/mL vial
69097-0802-32	
69097-0802-37	
00574-0827-01	
76519-1210-00	
00009-0086-01	
00009-0417-01	
00009-0520-01	
69097-0536-37	
69097-0537-31	
69097-0537-37	
50090-0330-00	
00409-6562-02	
00409-6562-22	
00143-9659-01	
62756-0017-40	
62756-0016-40	
00409-6557-01	
00409-6562-01	
00409-6562-20	
76420-0650-01	
00591-4128-79	
00009-0085-10	
00009-0086-10	
00574-0827-10	
00009-0520-10	
00009-0347-02	
62756-0015-40	
00143-9726-01	
00009-0417-02	
63874-1061-01	
00574-0820-01	
00574-0820-10	
64764-0300-20	Entyvio 300 mg vial
67457-0833-06	Fulphila 6 mg/0.6mL PFS
50242-0920-01	Hemlibra 30 mg/mL
50242-0922-01	Hemlibra 105 mg/0.7 mL
50242-0923-01	Hemlibra 150 mg/mL
50242-0921-01	Hemlibra 60 mg/0.4 mL
50242-0132-01	Herceptin 150 mg vial
50242-0132-10	

National Drug Code	Description
63459-0305-47	Herzuma 420 mg vial
63459-0303-43	Herzuma 150 mg vial
47335-0177-96	Ilumya 100 mg/mL PFS
47335-0177-95	Ilumya 100 mg/mL PFS
00069-0809-01	Inflectra 100 mg vial
55513-0132-01	Kanjinti 420 mg vial
55513-0141-01	Kanjinti 150 mg vial
55513-0206-01	Mvasi 100 mg/4 mL vial
55513-0207-01	Mvasi 400 mg/16 mL vial
55513-0190-01	Neulasta 6 mg/0.6 mL PFS
55513-0192-01	Neulasta 6 mg/0.6 mL PFS with on-body injector
00069-0324-01	Nyvepria 6 mg/0.6 mL PFS
67457-0847-44	Ogivri 420 mg vial
67457-0845-50	
67457-0991-15	Ogivri 150 mg vial
00006-5033-02	Ontruzant 150 mg vial
00003-3774-12	Opdivo 100 mg/10 ml vial
00003-3734-13	Opdivo 240 mg/24 ml vial
00003-3772-11	Opdivo 40 mg/4 mL vial
71336-1000-01	Onpattro 10 mg/5 mL vial
00003-2187-10	Orencia 250 mg vial
00003-2187-13	
55513-0710-01	Prolia 60 mg/1 mL PFS
00078-0435-61	Reclast 5 mg/100 mL vial
35356-0351-01	Reclast 5 mg/100 mL vial
57894-0030-01	Remicade 100 mg vial
00006-4305-01	Renflexis 100 mg vial
00006-4305-02	
50242-0051-10	Rituxan 100 mg/10 mL vial
50242-0051-21	
50242-0053-06	Rituxan 500 mg/50 mL vial
50242-0108-01	Rituxan Hycela 1,400-23,400 mg/11.7 mL vial
50242-0109-01	Rituxan Hycela 1,600-26,800 mg/13.4 mL vial
00069-0238-01	Ruxience 100 mg/10 mL vial
00069-0249-01	Ruxience 500 mg/50 mL vial
57894-0350-01	Simponi Aria 50 mg/4 mL vial
25682-0001-01	Soliris 300 mg/30 mL vial
57894-0060-03	Stelara 45 mg/0.5 mL PFS
57894-0060-02	Stelara 45 mg/0.5 mL vial
57894-0061-03	Stelara 90 mg/1 mL PFS
57894-0054-27	Stelara 130 mg/26 mL vial

National Drug Code	Description
66887-0004-01	Testopel 75 mg pellet
66887-0004-10	
66887-0004-20	
00069-0305-01	Trazimera 420 mg vial
00069-0306-01	
63459-0103-10	Truxima 100 mg/10 mL vial
63459-0104-50	Truxima 500 mg/50 mL vial
70114-0101-01	Udenyca 6 mg/0.6 mL PFS
25682-0022-01	Ultomiris 300 mg/30 mL vial
55513-0730-01	Xgeva 120 mg/1.7 mL vial
50242-0040-86	Xolair 150 mg vial
50242-0214-01	Xolair 75 mg PFS
50242-0215-01	Xolair 150 mg PFS
50242-0215-86	
61314-0866-01	Ziextenzo 6 mg/0.6 mL PFS
00069-0315-01	Zirabev 100 mg/4 mL vial
00069-0342-01	Zirabev 400 mg/16 mL vial
00409-4215-01	Zoledronic Acid 4 mg/5 mL vial
00409-4215-05	
16714-0815-01	
16729-0242-31	
23155-0170-31	
25021-0801-66	
43598-0330-11	
51991-0065-98	
54288-0100-01	
55111-0685-07	
55150-0266-05	
63323-0961-98	
67457-0390-54	
68001-0366-22	
68001-0366-25	
70860-0210-51	Zoledronic Acid 4 mg/100 mL vial
00409-4229-01	Zoledronic Acid 4 mg/100 mL infusion
23155-0186-31	
25021-0826-67	
25021-0826-82	
00078-0435-61	Zoledronic Acid 5 mg/100 mL vial
25021-0830-82	
43598-0331-11	
51991-0064-98	

National Drug Code	Description
55111-0688-52	Zoledronic Acid 5 mg/100 mL vial
63323-0966-00	
67457-0619-10	
00409-4228-01	Zoledronic Acid 5 mg/100 mL infusion
25021-0830-82	
67457-0794-10	
70860-0802-82	

Clinical Evidence

The aforementioned pharmaceuticals all have dosing parameters that support a maximum dosage per body weight or body surface area or a set maximal dosage independent of patient body size. These maximum doses are product-specific, and in some cases, disease state-specific and are defined in the U.S. Food and Drug Administration (FDA) approved product prescribing information and/or in national compendia and other peer reviewed resources. This policy creates an upper dose limit based on the clinical evidence and the 95th percentile for adult body weight (128 kg) and body surface area (2.59 meters^{2}) in the U.S. (adult male, 30 to 39 years, Fryar, 2016).

Clinical evidence supports the use of the medications listed in this policy up to maximum dosages based upon body surface area or patient weight, when used according to labeled indications or when otherwise supported by published clinical evidence.

Clinical evidence does not support the use of the medications listed in this policy beyond maximum dosages based upon body surface area or patient weight. Use of these agents beyond such established maximum dosages adds significantly to risk of adverse events without conferring additional clinical benefit.

References

1. Actemra [prescribing information]. South San Francisco, CA: Genentech, Inc.; June 2019.
2. Avastin [prescribing information]. South San Francisco, CA: Genentech, Inc.; June 2019.
3. Aveed [prescribing information]. Malvern, PA: Endo Pharmaceuticals; October 2019.
4. Avsola [prescribing information]. Thousand Oaks, CA: Amgen, Inc.; December 2019.
5. Beovu [prescribing information]. East Hanover, NJ; Novartis Pharmaceuticals Corporation; October 2019.
6. Cimzia [prescribing information]. Smyrna, GA: UCB, Inc.; September 2019.
7. Depo-testosterone [prescribing information]. New York, NY: Pharmacia & Upjohn Co.; August 2018.
8. Entyvio [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; May 2019.
9. Eylea [prescribing information]. Tarrytown, NY; Regeneron Pharmaceuticals, Inc.; August 2019.
10. Fulphila [prescribing information]. Rockford, IL: Mylan Institutional, LLC, May 2019.
11. Hemlibra [prescribing information]. South San Francisco, CA: Genentech, Inc.; October 2018.
12. Herceptin [prescribing information]. South San Francisco, CA: Genentech, Inc.; November 2018.
13. Herzuma [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; May 2019.
14. Ilumya [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; September 2019.
15. Inflectra [prescribing information]. New York, NY: Pfizer Labs; June 2019.
16. Kanjinti [prescribing information]. Thousand Oaks, CA: Amgen Inc.; October 2019.
17. Macugen [prescribing information]. San Dimas, CA; Gilead Sciences, Inc.; July 2016.

18. Lucentis [prescribing information]. South San Francisco, CA; Genentech, Inc.; March 2018.
19. Mvasi [prescribing information]. Thousand Oaks CA: Amgen Inc.; June 2019.
20. Neulasta [prescribing information]. Thousand Oaks, CA: Amgen Inc.; January 2020.
21. Nyvepria [prescribing information]. Lake Forest, IL: Pfizer Oncology; June 2020
22. Ogivri [prescribing information]. Steinhausen, Switzerland: Mylan GmbH; November 2019.
23. Onpattro [prescribing information]. Cambridge, MA: Alnylam Pharmaceuticals, Inc.; February 2020.
24. Ontruzant [prescribing information]. Whitehouse Station, NJ: Merck & Co., Inc.; January 2019.
25. Orencia [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Co.; March 2019.
26. Opdivo [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company, September 2019.
27. Prolia [prescribing information]. Thousand Oaks, CA: Amgen Inc.; July 2019.
28. Reclast [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2017.
29. Remicade [prescribing information]. Horsham, PA: Janssen Biotech Inc.; June 2018.
30. Renflexis [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; February 2020.
31. Rituxan [prescribing information]. South San Francisco, CA: Genentech, Inc.; January 2020.
32. Rituxan Hycela [prescribing information]. South San Francisco, CA: Genentech, Inc.; December 2019.
33. Ruxience [prescribing information]. New York, NY: Pfizer Labs; July 2019.
34. Simponi Aria [prescribing information]. Horsham, PA: Janssen Biotech, Inc.; February 2021.
35. Soliris [prescribing information]. Boston, MA: Alexion Pharmaceuticals, Inc.; June 2019.
36. Stelara [prescribing information]. Horsham, PA: Janssen Biotech, Inc. October 2019.
37. Testopel [prescribing information]. Malvern, PA: Endo Pharmaceuticals, Inc.; August 2018.
38. Trazimera [prescribing information]. New York, NY: Pfizer Inc.; November 2019.
39. Truxima [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2019.
40. Udenyca [prescribing information]. Redwood City, CA: Coherus BioSciences, Inc, November 2019.
41. Ultomiris [prescribing information]. Boston, MA: Alexion Pharmaceuticals, Inc.; October 2019.
42. Xgeva [prescribing information]. Thousand Oaks, CA: Amgen Inc.; February 2020.
43. Xolair [prescribing information]. South San Francisco, CA: Genentech, Inc., April 2001.
44. Ziextenzo [prescribing information]. Princeton, NJ: Sandoz, Inc.; November 2019.
45. Zirabev [prescribing information]. New York, NY: Pfizer Inc.; January 2020.
46. Zometa [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2018.
47. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2020.
48. Constantine S. Tam, Susan O'Brien, William Wierda, Hagop Kantarjian, Sijin Wen, Kim-Anh Do, Deborah A. Thomas, Jorge Cortes, Susan Lerner, and Michael J. Keating. Long-term results of the fludarabine, cyclophosphamide, and rituximab regimen as initial therapy of chronic lymphocytic leukemia. Blood 2008; 112: 975-980.
49. Fryar CD, Gu Q, Ogden CL, Flegal KM. Anthropometric Reference Data for Children and Adults: United States, 2011-2014. Vital Health Stat 3. 2016 Aug;(39):1-46.
50. Reimbursement Codes [database online]. Rocky Hill, CT: RJ Health Systems International, LLC.; 2020.

Policy History/Revision Information

Date	Summary of Changes
02/18/2022	Coverage Rationale *Maximum Allowed Quantities by HCPCS Units* • Corrected maximum allowed amount for HCPCS code J2506

01/01/2022	Applicable Codes
	• Updated list of applicable HCPCS codes to reflect annual edits:
	  ○ Added J2506
	  ○ Removed J2505
	Supporting Information
	• Archived previous policy version CSIND0034.02

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.