Maximum Dosage and Frequency

Policy Number: 2020D0034Z
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Instructions for Use

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Community Plan Policy

- Maximum Dosage and Frequency

Coverage Rationale

See Benefit Considerations

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®)
- bevacizumab (Avastin®)
- bevacizumab-awwb (Mvasi™)
- bevacizumab-bvzr (Zirabev®)
- 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®)
- pegfilgrastim (Neulasta®)
- pegfilgrastim-cbqv (Udenyca®)
- pegfilgrastim-jmdb (Fulphila™)
- pegfilgrastim-bmez (Ziextenzo®)
- ravulizumab-cwvz (Ultomiris®)
- rituximab (Rituxan®)
- rituximab-pvvr (Ruxience™)
- rituximab-abbs (Truxima®)

- rituximab and hyaluronidase (Rituxan Hycela®)
- testosterone cypionate (Depo-Testosterone®)
- testosterone enanthate (Delatestryl®)
- 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.

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)
Delatestryl	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		6mg/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)

Medication Name		Diagnosis	Maximum Dosage Per Administration	HCPCS Code	Maximum Allowed
Brand	Generic				
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)
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 MCPCs units (1 mg per unit)
Neulasta	pegfilgrastim		6 mg	J2505	1 HCPCS unit (6 mg per unit)
Fulphila	pegfilgrastim-jmdb		6 mg	Q5108	12 HCPCS units (0.5mg per unit)
Udenyca	pegfilgrastim-cbqv		6 mg	Q5111	12 HCPCS units (0.5mg per unit)
Ziextenzo	pegfilgrastim-bmez		6 mg	Q5120	12 HCPCS units (0.5mg per unit)
Opdivo	nivolumab		480 mg	J9299	480 HCPCS units (1 mg per unit)
Orencia	abatacept		1000 mg	J0129	100 HCPCs units (10 mg per unit)
Reclast	zoledronic acid		5 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)
Zometa	zoledronic acid		4 mg	J3489	5 HCPCS units (1 mg per unit)
Avsola	infliximab-axxq		10 mg/kg	Q5121	128 HCPCS units (10 mg per unit)
Inflectra	infliximab-dyyb		10 mg/kg	Q5103	128 HCPCS units (10 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)
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				
Ruxience	rituximab-pvvr		1,225 mg	Q5119	123 HCPCS units (10 mg per unit)
Truxima	rituximab-abbs		1,225 mg	Q5115	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	256 HCPCs units (1 mg per unit)
Soliris	eculizumab	PNH	900 mg	J1300	90 HCPCS units (10 mg per unit)
		aHUS	1200 mg	J1300	120 HCPCS units (10 mg per unit)
		MG	1200 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)
Xolair	omalizumab	Chronic Urticaria	300 mg	J2357	60 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 NCD 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 vials	50242-0135-01 50242-0136-01 50242-0137-01	40 mL
Avastin	bevacizumab		100 mg/4mL vials	50242-0060-01 50242-0060-10	77 mL
			400 mg/16 mL vials	50242-0061-01 50242-0061-10	77 mL
Mvasi	bevacizumab-awwb		100 mg/4mL vials	55513-0206-01	77 mL
			400 mg/16 mL vials	55513-0207-01	77 mL
Zirabev	bevacizumab-bvzr		100 mg/4mL vials	00069-0315-01	77 mL
			400 mg/16 mL vials	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 200mg 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
Delatestryl	testosterone enanthate		200 mg/mL	00134-9750-01	2 mL
Depo-Testosterone	Testosterone cypionate		200 mg/mL	00009-0085-10 00009-0086-01 00009-0086-10 00009-0347-02 00009-0417-01 00009-0417-02 00009-0520-01 00009-0520-10 00143-9659-01 00143-9726-01 00409-6557-01 00409-6562-01 00409-6562-02 00409-6562-20 00409-6562-22 00517-1830-01 00574-0820-01 00574-0820-10 00574-0827-01 00574-0827-10 00591-4128-79 50090-0330-00 52536-0625-01 52536-0625-10 62756-0015-40 62756-0016-40 62756-0017-40 63874-1061-01	2 mL
				64980-0467-99 69097-0536-37 69097-0537-31 69097-0537-37 69097-0802-32 69097-0802-37 76420-0650-01 76519-1210-00	
Entyvio	vedolizumab		300 mg vial	64764-0300-20	1 vial
Hemlibra	emicizumab-kxwh		30 mg/mL	50242-0920-01	768 mg
			105 mg/0.7 mL	50242-0922-01	
			150 mg/mL	50242-0923-01	
			60 mg/0.4 mL	50242-0921-01	

Medication Name		Diagnosis	How Supplied	National Drug Code	Maximum Allowed
Brand	Generic				
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
Fulphila	pegfilgrastim-jmdb		6 mg/0.6mL PFS	67457-0833-06	0.6 mL
Udenyca	pegfilgrastim-cbqv		6 mg/0.6mL PFS	70114-0101-01	0.6 mL
Ziextenzo	pegfilgrastim-bmez		6 mg/0.6mL PFS	61314-0866-01	0.6 mL
Opdivo	nivolumab		100 mg/10 mL vials	00003-3774-12	40 mL
			240 mg/24 mL vials	00003-3734-13	48 mL
			40 mg/4 mL vials	00003-3772-11	8 mL
Onpattro	patisiran		10 mg/5 mL vials	71336-1000-01	15 mL
Orencia	abatacept		250 mg vials	00003-2187-10 00003-2187-13	4 vials
Remicade	infliximab		100 mg vials	57894-0030-01	13 vials
Avsola	infliximab-axxq		100 mg vials	55513-0670-01	13 vials
Renflexis	infliximab-abda		100 mg vials	00006-4305-01 00006-4305-02	13 vials
Inflectra	infliximab-dyyb		100 mg vials	00069-0809-01	13 vials
Rituxan	rituximab		100 mg/10 mL vials	50242-0051-01 50242-0051-21	40 mL
			500 mg/50 mL vials	50242-0053-06	130 mL
Ruxience	rituximab-pvvr		100 mg/10 mL vials	00069-0238-01	40 mL
			500 mg/50 mL vials	00069-0249-01	130 mL

Medication Name		Diagnosis	How Supplied	National Drug Code	Maximum Allowed
Brand	Generic				
Truxima	rituximab-abbs		100 mg/10 mL vials	63459-0103-10	40 mL
			500 mg/50 mL vials	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 vials	25682-0001-01	90 mL
		aHUS	300 mg/30 mL vials	25682-0001-01	120 mL
		MG	300 mg/30 mL vials	25682-0001-01	120 mL
Stelara	ustekinumab		45 mg/0.5 mL PFS	57894-0060-03	0.5 mL
			45 mg/0.5 mL vials	57894-0060-02	0.5 mL
			90 mg/1 mL PFS	57894-0061-03	1 mL
		Crohn's Disease	130 mg/26 mL vials	57894-0054-27	104 mL
		Ulcerative Colitis	130 mg/26 mL vials	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 vials	25682-0022-01	360 mL
Xolair	omalizumab	Asthma	150 mg vials	50242-0040-62	2 vials
			150 mg PFS	50242-0215-01 50242-0215-86	2 mL
			75 mg PFS	50242-0214-01	1 mL
		Chronic Urticaria	150 mg vials	50242-0040-86	2 vials
			150 mg PFS	50242-0215-01 50242-0215-86	2 mL
			75 mg PFS	50242-0214-01	1 mL
Prolia	denosumab	Osteoporosis	60 mg/1 mL PFS	55513-0710-01	1 mL
Xgeva	denosumab	Oncology	120 mg/1.7 mL vials	55513-0730-01	1.7 mL
Reclast Zometa	zoledronic acid		4 mg/5 mL vials	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 55150-0266-05 63323-0961-98 67457-0390-54 68001-0366-22 68001-0366-25	5 mL
			4 mg/100 mL vials	70860-0210-51	100 mL

Medication Name		Diagnosis	How Supplied	National Drug Code	Maximum Allowed
Brand	Generic				
Reclast Zometa	zoledronic acid		4 mg/100 mL infusion	00409-4229-01 23155-0186-31 25021-0826-67 25021-0826-82	100 mL
			5mg/100 mL vials	00078-0425-61 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 Oxford Health Plans 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.
Aveed	testosterone undecanoate		The recommended dose is 750mg initially, followed by 750mg after 4 weeks, then 750mg every 10 weeks thereafter.
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 ≤ 90kg)	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 > 90kg)	Administered every other week.
Delatestryl	testosterone enanthate		For replacement therapy, 50 mg to 400 mg every 2 to 4 weeks, not to exceed 400 mg per month.
Depo-testosterone	testosterone cypionate		For replacement in the hypogonadal male, 50 mg to 400 mg every 2 to 4 weeks, not to exceed 400 mg per month.
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.

Medication Name		Diagnosis	Maximum Frequency
Brand	Generic		
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.
Avsola Inflectra Remicade Renflexis	infliximab-axxq infliximab-dyyb infliximab 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.
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.
		Psoriatic Arthritis	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.
Prolia	denosumab	Osteoporosis	Administered once every 6 months.
Simponi Aria	golimumab	Ankylosing Spondylitis	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	aHUS	Administered once weekly for 5 doses, then every 2 weeks thereafter.
		MG	Administered once weekly for 5 doses, then every 2 weeks thereafter.
		NMOSD	Administered once weekly for 5 doses, then every 2 weeks thereafter.
		PNH	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	Administered subcutaneously – initially and 4 weeks later, then every 12 weeks thereafter.

Medication Name		Diagnosis	Maximum Frequency
Brand	Generic		
Stelara	ustekinumab	Crohn's Disease	Administered intravenously (IV) initially one time, then subcutaneously 8 weeks after the initial IV dose, then once every 8 weeks thereafter.
		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 150mg to 450mg subcutaneously every 3 to 6 months. The usual dosage is as follows: Implant two 75mg pellets for each 25mg testosterone propionate required weekly. Thus when a patient requires injections of 75mg per week, it is usually necessary to implant 450mg (6 pellets). With injections of 50mg per week, implantation of 300mg (4 pellets) may suffice for approximately three months.
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.

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 the member specific benefit plan document 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
J2505	Injection, pegfilgrastim, 6 mg
J3121	Injection, testosterone enanthate, 1 mg
J3145	Injection, testosterone undecanoate, 1 mg

HCPCS Code	Description
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
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
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 50242-0060-10	Avastin 100 mg/4 mL vial
50242-0061-01 50242-0061-10	Avastin 400 mg/16 mL vial
67979-0511-43	Aveed 750 mg/3 mL vial
55513-0670-01	Avsola 100 mg vial
50474-0700-62	Cimzia 2 x 200mg kit
50474-0710-79	Cimzia 2 x 200mg/ml prefilled syringe (PFS) kit
50474-0710-81	Cimzia 6 x 200 mg/ml PFS kit

National Drug Code	Description
00134-9570-01	Delatestryl (testosterone enanthate) 200 mg/mL vial
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	Depo-Testosterone (testosterone cypionate) 200 mg/mL vial
64764-0300-20	Entyvio 300 mg vial
67457-0833-06	Fulphila 6 mg/0.6ml PFS
50242-0922-01	Hemlibra 105mg/0.7 L
50242-0923-01	Hemlibra 150mg/mL
50242-0920-01	Hemlibra 30 mg/mL
50242-0921-01	Hemlibra 60 mg/0.4 mL
50242-0132-01 50242-0132-10	Herceptin 150 mg vial
63459-0303-43	Herzuma 150 mg vial

National Drug Code	Description
63459-0305-47	Herzuma 420 mg vial
47335-0177-96 47335-0177-95	Ilumya 100mg/mL PFS
00069-0809-01	Inflectra 100 mg vial
55513-0141-01	Kanjinti 150 mg vial
55513-0132-01	Kanjinti 420 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
67457-0991-15	Ogivri 150 mg vial
67457-0847-44 67457-0845-50	Ogivri 420 mg vial
71336-1000-01	Onpattro 10 mg/5 mL 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
00003-2187-10 00003-2187-13	Orencia 250 mg vial
55513-0710-01	Prolia 60 mg/1 mL PFS
00078-0435-61	Reclast 5 mg/100 mL solution in vial
35356-0351-01	Reclast 5 mg/100 mL solution in vial
57894-0030-01	Remicade 100 mg vial
00006-4305-01 00006-4305-02	Renflexis 100 mg vial
50242-0051-10 50242-0051-21	Rituxan 100 mg/10 mL vial
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
57894-0054-27	Stelara 130 mg/26 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
66887-0004-01 66887-0004-10 66887-0004-20	Testopel 75 mg pellet

National Drug Code	Description
00069-0305-01 00069-0306-01	Trazimera 420 mg vial
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
50242-0215-01 50242-0215-86	Xolair 150 mg PFS
50242-0040-86	Xolair 150 mg vial
50242-0214-01	Xolair 75 mg PFS
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
00409-4229-01 23155-0186-31 25021-0826-67 25021-0826-82	Zoledronic Acid 4 mg/100 mL infusion
70860-0210-51	Zoledronic Acid 4 mg/100 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 55150-0266-05 63323-0961-98 67457-0390-54 68001-0366-22 68001-0366-25	Zoledronic Acid 4 mg/5 mL vial
00409-4228-01 25021-0830-82 67457-0794-10 70860-0802-82	Zoledronic Acid 5 mg/100 mL infusion
00078-0435-61 25021-0830-82 43598-0331-11 51991-0064-98 55111-0688-52 63323-0966-00 67457-0619-10	Zoledronic Acid 5 mg/100 mL vial

Benefit Considerations

Some Certificates of Coverage allow for coverage of experimental/investigational/unproven treatments for life-threatening illnesses when certain conditions are met. The member specific benefit plan document must be consulted to make coverage decisions for this service. Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances when certain conditions are met. Where such mandates apply, they supersede language in the benefit document or in the medical or drug policy. Benefit coverage for an otherwise unproven service for the treatment of serious rare diseases may occur when certain conditions are met. Refer to the Policy and Procedure addressing the treatment of serious rare diseases.

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.

Centers for Medicare and Medicaid Services (CMS)

Medicare does not have a National Coverage Determination (NCD) that specifically address maximum dosage and frequency for any medication. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist at this time.

In general, Medicare may cover outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. Refer to the Medicare Benefit Policy Manual, Chapter 15, §50 - Drugs and Biologicals. (Accessed March 12, 2020)

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Policy History/Revision Information

Date	Summary of Changes

10/01/2020	**Coverage Rationale**
	• Revised *Maximum Allowed Quantities for National Drug Code (NDC) Billing* for:
	  ○ Herzuma: Added National Drug Code (NDC) 63459-0307-41
	  ○ Ontruzant: Added 420 mg vial
	  ▪ NCDs: 00006-5034-01 and 00006-5034-02
	  ▪ Maximum allowed: 3 vials
	  ○ Ilumya: Added NDCs 47335-0177-01 and 47335-0177-10
	  ○ Simponi Aria: Replaced maximum allowed amount of "*21* mL" with "*24* mL"
	Supporting Information
	• Archived previous policy version 2020D0034Y

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. 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.

This Medical Benefit Drug Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. 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.