

# Maximum Dosage and Frequency (for Pennsylvania Only)

**Policy Number:** CSPA2024D0034AL  
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<b>Related Policies</b>
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• <a href="#">Oncology Medication Clinical Coverage (for Pennsylvania Only)</a>
• <a href="#">Rituximab (Riabni®, Rituxan®, Ruxience®, &amp; Truxima®) (for Pennsylvania Only)</a>
• <a href="#">RNA-Targeted Therapies (Amvuttra® and Onpatro®)</a>

## Application

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

## 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®)
- atezolizumab (Tecentriq®)
- avelumab (Bavencio®)
- benralizumab (Fasenra®)
- bevacizumab (Avastin®)
- bevacizumab-adcd (Vegzelma®)
- bevacizumab-awwb (Mvasi™)
- bevacizumab-bvzr (Zirabev™)
- bevacizumab-maly (Almysys®)
- brolocizumab-dbll (Beovu®)
- canakinumab (Ilaris®)
- cemiplimab-rwlc (Libtayo®)
- certolizumab pegol (Cimzia®)
- denosumab (Prolia® & Xgeva®)
- durvalumab (Imfinzi®)
- eculizumab (Soliris®)
- edaravone (Radicava®)
- efgartigimod alfa-fcab (Vyvgart®)
- efgartigimod alfa and hyaluronidase-qvfc (Vyvgart® Hytrulo)
- eflapegrastim-xnst (Rolvedon™)
- emicizumab-kxwh (Hemlibra®)
- eptinezumab-jjmr (Vyepti®)
- faricimab-svoa (Vabysmo™)
- golimumab (Simponi Aria®)
- inclisiran (Leqvio®)
- i-axxq (Avsola™)
- infliximab-dyyb (Inflectra®)
- infliximab-abda (Renflexis®)
- ipilimumab (Yervoy®)
- mepolizumab (Nucala®)
- nivolumab (Opdivo®)
- ocrelizumab (Ocrevus®)
- omalizumab (Xolair®)
- patisiran (Onpatro®)
- pegcetacoplan (Syfovre™)
- pegfilgrastim (Neulasta®)
- pegfilgrastim-apgf (Nyvepria™)
- pegfilgrastim-cbqv (Udenyca™)
- pegfilgrastim-fpgk (Stimufend®)
- pegfilgrastim-jmdb (Fulphila™)
- pegfilgrastim-pbbk (Fylnetra®)
- pegfilgrastim-bmez (Ziextenzo™)
- pegloticase (Krystexxa®)
- pembrolizumab (Keytruda®)
- ranibizumab (Lucentis®)
- ranibizumab-nuna (Byooviz™)
- ranibizumab-eqrn (Cimerli™)
- ravulizumab-cwvz (Ultomiris®)
- risankizumab-rzaa (Skyrizi®)
- reslizumab (Cinqair®)
- rituximab (Rituxan®)
- rituximab-pvvr (Ruxience®)
- rituximab-abbs (Truxima®)
- rituximab-arrr (Riabni™)
- rituximab and hyaluronidase rituxan (Hycela®)
- rozanolixizumab-noli (Rystiggo®)
- spesolimab-sbzo (Spevigo®)

- testosterone cypionate (Depo-Testosterone®)
- testosterone enanthate
- testosterone pellets (Testopel®)
- testosterone undecanoate (Aveed®)
- tezepelumab-ekko (Tezspire®)
- tildrakizumab-asmn (Ilumya™)
- tocilizumab (Actemra®)
- tofersen (Qalsody™)
- trastuzumab (Herceptin®)
- trastuzumab-anns (Kanjinti™)
- trastuzumab-dkst (Ogivri™)
- trastuzumab-dttb (Ontruzant™)
- trastuzumab-pkrb (Herzuma®)
- trastuzumab-qyyp (Trazimera™)
- ustekinumab (Stelara®)
- vedolizumab (Entyvio®)
- vutrisiran (Amvuttra™)
- zoledronic acid (Reclast®)

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 95<sup>th</sup> percentile for adult body weight (140 kg) and body surface area (2.71 meters<sup>2</sup>) in the U.S. (adult male, 30 to 39 years, Fryar, 2021).<sup>59</sup> 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 > 140 kg or body surface area > 2.71 meters<sup>2</sup>.

## Maximum Allowed Quantities by HCPCS Units

Medication Name		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	240 HCPCS units (10 mg per unit)
Vegzelma	bevacizumab-adcd	15 mg/kg	Q5129	240 HCPCS units (10 mg per unit)
Mvasi	bevacizumab-awwb	15 mg/kg	Q5107	240 HCPCS units (10 mg per unit)
Zirabev	bevacizumab-bvzr	15 mg/kg	Q5118	240 HCPCS units (10 mg per unit)
Alymsys	bevacizumab-maly	15 mg/kg	Q5126	240 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)
Cinqair	reslizumab	3 mg/kg	J2786	500 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)
Fasenra	benralizumab	30 mg	J0517	30 HCPCS units (1 mg per unit)
Hemlibra	emicizumab-kxwh	6 mg/kg	J7170	1,680 HCPCS units (0.5 mg per unit)

Medication Name		Maximum Dosage Per Administration	HCPCS Code	Maximum Allowed
Brand	Generic			
Herceptin	trastuzumab	8 mg/kg	J9355	126 HCPCS units (10 mg per unit)
Herzuma	trastuzumab- pkrb	8 mg/kg	Q5113	126 HCPCS units (10 mg per unit)
Kanjinti	trastuzumab- anns	8 mg/kg	Q5117	126 HCPCS units (10 mg per unit)
Ogivri	trastuzumab- dkst	8 mg/kg	Q5114	126 HCPCS units (10 mg per unit)
Ontruzant	trastuzumab-dttb	8 mg/kg	Q5112	126 HCPCS units (10 mg per unit)
Trazimera	trastuzumab- qyyp	8 mg/kg	Q5116	126 HCPCS units (10 mg per unit)
Ilaris	canakinumab	300 mg	J0638	300 HCPCS units (1 mg per unit)
Ilumya	tildrakizumab- asmn	100 mg	J3245	100 HCPCS units (1 mg per unit)
Leqvio	incisiran	284 mg	J1306	284 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)
Fylnetra	pegfilgrastim- pbbk	6 mg	Q5130	12 HCPCS units (0.5mg per unit)
Stimufend	pegfilgrastim- fpgk	6 mg	Q5127	12 HCPCS units (0.5mg 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)
Rolvedon	eflapegrastim- xnst	13.2 mg	J1449	132 HCPCS units (0.1mg per unit)
Krystexxa	pegloticase	8 mg	J2507	8 HCPCS units (1mg per unit)
Nucala	mepolizumab	300 mg	J2182	300 HCPCS units (1 mg per unit)
Ocrevus	ocrelizumab	600 mg	J2350	600 HCPCS units (1 mg 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)

Medication Name		Maximum Dosage Per Administration	HCPCS Code	Maximum Allowed
Brand	Generic			
Zoledronic Acid	zoledronic acid	5 mg	J3489	5 HCPCS units (1 mg per unit)
		4 mg	J3489	5 HCPCS units (1 mg per unit)
Avsola	infliximab-axxq	10 mg/kg	Q5121	150 HCPCS units (10 mg per unit)
Inflectra	infliximab-dyyb	10 mg/kg	Q5103	150 HCPCS units (10 mg per unit)
Remicade	infliximab	10 mg/kg	J1745	150 HCPCS units (10 mg per unit)
Renflexis	infliximab-abda	10 mg/kg	Q5104	150 HCPCS units (10 mg per unit)
Onpattro	patisiran	30 mg	J0222	300 HCPCS units (0.1 mg per unit)
Amvuttra	vutrisiran	25 mg	J0225	25 HCPCS units (1 mg per unit)
Prolia	denosumab	60 mg	J0897	60 HCPCS units (1 mg per unit)
Xgeva	denosumab	120 mg	J0897	120 HCPCS units (1 mg per unit)
Qalsody	tofersen	100 mg	J1304	100 HCPCS units (1 mg per unit)
Radicava	edaravone	60 mg	J1301	60 HCPCS units (1 mg per unit)
Rituxan	rituximab	500mg/m <sup>2</sup>	J9312	150 HCPCS units (10 mg per unit)
		1355 mg	J9312	150 HCPCS units (10 mg per unit)
Ruxience	rituximab-pvvr	500mg/m <sup>2</sup>	Q5119	150 HCPCS units (10 mg per unit)
		1355 mg	J9312	150 HCPCS units (10 mg per unit)
Truxima	rituximab-abbs	500mg/m <sup>2</sup>	Q5115	150 HCPCS units (10 mg per unit)
		1355 mg	J9312	150 HCPCS units (10 mg per unit)
Riabni	rituximab-arrx	500mg/m <sup>2</sup>	Q5123	150 HCPCS units (10 mg per unit)
		1355 mg	J9312	150 HCPCS units (10 mg per unit)
Rituxan Hycela	rituximab and hyaluronidase	1,600 mg	J9311	160 HCPCS units (10 mg per unit)
Rystiggo	rozanolizumab -noli	840 mg	J9333	840 HCPCS units (1 mg per unit)
Simponi Aria	golimumab	80 mg/m <sup>2</sup>	J1602	300 HCPCS units (1 mg per unit)
		2 mg/kg	J1602	300 HCPCS units (1 mg per unit)

Medication Name		Maximum Dosage Per Administration	HCPCS Code	Maximum Allowed
Brand	Generic			
Soliris	eculizumab	900 mg	J1300	90 HCPCS units (10 mg per unit)
		1200 mg	J1300	120 HCPCS units (10 mg per unit)
Spevigo	spesolimab-sbzo	900 mg	J1747	900 HCPCS units (1 mg per unit)
Stelara	ustekinumab	90 mg	J3357	90 HCPCS units (1 mg per unit)
		520 mg	J3358	520 HCPCS units (1 mg per unit)
Testopel	testosterone pellet	450 mg	S0189	6 HCPCS units (75 mg per unit)
Tezspire	tezepelumab-ekko	210 mg	J2356	210 HCPCS units (1mg per unit)
Ultomiris	ravulizumab-cwvz	3,600 mg	J1303	360 HCPCS units (10 mg per unit)
Vyepti	eptinezumab-jjmr	300 mg	J3032	300 HCPCS units (1 mg per unit)
Vyvgart	efgartigimod alfa-fcab	1200 mg	J9332	600 HCPCS units (2mg per unit)
Vyvgart Hytrulo	efgartigimod alfa and hyaluronidase-qvfc	1,008 mg / 11,200 units (1,008 mg efgartigimod alfa and 11,200 units hyaluronidase)	J9334	504 HCPCS units (2mg per unit)
Xolair	omalizumab	375 mg	J2357	90 HCPCS units (5 mg per unit)
		300 mg	J2357	60 HCPCS units (5 mg per unit)
		600 mg	J2357	120 HCPCS units (5 mg per unit)
Bavencio	avelumab	800 mg	J9023	80 HCPCS units (10 mg per unit)
Imfinzi	durvalumab	1,500 mg	J9173	150 HCPCS units (10 mg per unit)
Keytruda	pembrolizumab	400 mg	J9271	400 HCPCS units (1 mg per unit)
Libtayo	cemiplimab-rwlc	350 mg	J9119	350 HCPCS units (1 mg per unit)
Tecentriq	atezolizumab	1,680 mg	J9022	168 HCPCS units (10 mg per unit)
Yervoy	ipilimumab	10 mg/kg	J9228	1400 HCPCS units (1 mg per unit)
Skyrizi	risankizumab-rzaa	600 mg	J2327	600 HCPCS units (1 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		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	12 mL
		400 mg/16 mL vials	50242-0061-01 50242-0061-10	96 mL
Vegzelma	bevacizumab-adcd	100 mg/4 mL vials	32228-0011-01 32228-0011-02	12 mL
		400 mg/16 mL vials	32228-0011-03 32228-0011-04	96 mL
Mvasi	bevacizumab-awwb	100 mg/4mL vials	55513-0206-01	12 mL
		400 mg/16 mL vials	55513-0207-01	96 mL
Zirabev	bevacizumab-bvzr	100 mg/4mL vials	00069-0315-01	12 mL
		400 mg/16 mL vials	00069-0342-01	96 mL
Alymsys	bevacizumab-maly	100mg/4mL vials	70121-1754-01 70121-1754-07	12 mL
		400mg/16mL vials	70121-1755-01 70121-1755-07	96 mL
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
Cinqair	reslizumab	100 mg/10 mL vials	59310-0610-31	50 mL
N/A	testosterone enanthate	200 mg/mL	00143-9750-01 00574-0821-05 00591-3221-26	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 64980-0467-99 69097-0536-37 69097-0537-31 69097-0537-37 69097-0802-32 69097-0802-37 76420-0650-01 76519-1210-00	2 mL

Medication Name		How Supplied	National Drug Code	Maximum Allowed
Brand	Generic			
Depo-Testosterone	testosterone cypionate	200 mg/mL		2 mL
Entyvio	vedolizumab	300 mg vial	64764-0300-20	1 vial
Fasenra	benralizumab	30 mg/mL pre-filled pen	00310-1830-30	1 mL
		30 mg/mL PFS	00310-1730-30	1 mL
		10 mg/0.5 mL PFS	00310-1745-01	0.5 mL
Hemlibra	emicizumab-kxwh	30 mg/mL	50242-0920-01	1 mL
		105 mg/0.7 mL	50242-0922-01	0.7 mL
		150 mg/mL	50242-0923-01	6 mL
		60 mg/0.4 mL	50242-0921-01	0.4 mL
Herceptin	trastuzumab	150 mg vial	50242-0132-01 50242-0132-10	8 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
Ilaris	canakinumab	150 mg/mL vials	00078-0734-61	2 mL
Ilumya	tildrakizumab-asmn	100 mg/mL PFS	47335-0177-95	1 mL
Leqvio	inclisiran	284 mg/1.5 mL PFS	00078-1000-60	1.5 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/0.6mL PFS	00069-0324-01	0.6 mL
Fulphila	pegfilgrastim-jmdb	6 mg/0.6mL PFS	67457-0833-06	0.6 mL
Fylnetra	pegfilgrastim-pbbk	6mg/0.6mL PFS	70121-1627-01	0.6 mL
Stimufend	pegfilgrastim-fpgk	6mg/0.6mL PFS	65219-0371-10	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
Rolvedon	eflapegrastim-xnst	13.2 mg/0.6mL PFS	76961-0101-01	0.6 mL
Krystexxa	peglicase	8 mg/mL vials	75987-0080-10	1 mL



Medication Name		How Supplied	National Drug Code	Maximum Allowed
Brand	Generic			
Nucala	mepolizumab	100 mg vials	00173-0881-01	3 vials
		40mg/0.4mL PFS	00173-0904-42	0.4 mL
		100mg/mL PFS	00173-0892-01	3 mL
		100mg/mL PFS	00173-0892-42	3 mL
Ocrevus	ocrelizumab	300mg/10mL vial	50242-0150-01	20 mL
Opdivo	nivolumab	100 mg/10 mL vials	00003-3774-12	40 mL
		120mg/12 mL vials	00003-3756-14	48 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
Amvuttra	vutrisiran	25 mg/0.5 mL PFS	71336-1003-01	0.5 mL
Orencia	abatacept	250 mg vials	00003-2187-10 00003-2187-13	4 vials
Remicade	infliximab	100 mg vials	57894-0030-01	14 vials
Avsola	infliximab-axxq	100 mg vials	55513-0670-01	14 vials
Renflexis	infliximab-abda	100 mg vials	00006-4305-01 00006-4305-02	14 vials
Inflectra	infliximab-dyyb	100 mg vials	00069-0809-01	14 vials
Rituxan	rituximab	100 mg/10 mL vials	50242-0051-10 50242-0051-21	40 mL
		500 mg/50 mL vials	50242-0053-06	150 mL
Ruxience	rituximab-pvvr	100 mg/10 mL vials	00069-0238-01	40 mL
		500 mg/50 mL vials	00069-0249-01	150 mL
Truxima	rituximab-abbs	100 mg/10 mL vials	63459-0103-10	40 mL
		500 mg/50 mL vials	63459-0104-50	150 mL
Riabni	rituximab-arrx	100 mg/10 mL vials	55513-0224-01	40 mL
		500 mg/50 mL vials	55513-0326-01	150 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
Rystiggo	rozanolizumab -noli	280 mg/2 mL vials	50474-0980-79	6 mL
Simponi Aria	golimumab	50 mg/4 mL	57894-0350-01	24 mL
Soliris	eculizumab	300 mg/30 mL vials	25682-0001-01	120 mL
Spevigo	spesolimab-sbzo	450 mg/7.5 mL vials	00597-0035-10	15 mL
		150 mg/mL PFS	00597-0620-20	2 mL
Stelara Stelara	ustekinumab 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
		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
Tezspire	tezepelumab-ekko	210 mg/1.91 mL pre-filled pen	55513-0123-01	1.91 mL
		210 mg/1.91 mL PFS	55513-0112-01	1.91 mL



Medication Name		How Supplied	National Drug Code	Maximum Allowed
Brand	Generic			
Ultomiris	ravulizumab-cwvz	300 mg/3 mL vials	25682-0025-01	9 mL
		1,100 mg/11 mL vials	25682-0028-01	44 mL
Vyepti	eptinezumab-jjmr	100 mg/mL vials	67386-0130-51	3 mL
Vyvgart	efgartigimod alfa-fcab	400 mg/20 mL vials	73475-3041-05	60 mL
Vyvygart Hytrulo	efgartigimod alfa and hyaluronidase-qvfc	1,008 mg, 11,200 units hyaluronidase / 5.6 mL	73475-3102-03	5.6 mL
Xolair	omalizumab	150 mg vials	50242-0040-62	4 vials
		300 mg/2 mL PFS	50242-0227-01	4 mL
		150 mg vial/mL PFS	50242-0215-01	4 mL
		75 mg/0.5 mL PFS	50242-0214-01	0.5 mL
		75 mg/0.5 mL PFS	50242-0214-03	0.5 mL
		150 mg/mL PFS	50242-0215-03	4 mL
		300 mg/2 mL auto-injector	50242-227-55	4 mL
		150 mg /mL auto-injector	50242-215-55	4 mL
		75 mg/0.5 mL auto-injector	50242-214-55	0.5 mL
Prolia	denosumab	60 mg/1 mL PFS	55513-0710-01	1 mL
Xgeva	denosumab	120 mg/1.7 mL vials	55513-0730-01	1.7 mL
Qalsody	tofersen	100 mg/15 mL vials	64406-0109-01	15 mL
Radicava	edaravone	30 mg/100 mL bags	70510-2171-01 70510-2171-02	200 mL
Reclast	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
		4 mg/100 mL infusion	00409-4229-01 23155-0186-31 25021-0826-67 25021-0826-82	100 mL
		5mg/100 mL vials	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
Bavencio	avelumab	200mg/10mL vials	44087-3535-01	40 mL
Imfinzi	durvalumab	120 mg/2.4 mL vials	00310-4500-12	9.6 mL
		500 mg/10 mL vials	00310-4611-50	30 mL

Medication Name		How Supplied	National Drug Code	Maximum Allowed
Brand	Generic			
Keytruda	pembrolizumab	50 mg vials	00006-3029-01 00006-3029-02	8 vials
		100 mg/4 mL vials	00006-3026-01 00006-3026-02 00006-3026-04	16 mL
Libtayo	cemiplimab-rwlc	350mg/7mL vials	61755-0008-01	7 mL
Tecentriq	atezolizumab	840mg/14mL vials	50242-0918-01	28 mL
		1200mg/20mL vials	50242-0917-01	40 mL
Yervoy	ipilimumab	50mg/10mL vials	00003-2327-11	30 mL
		200mg/40mL vials	00003-2328-22	280 mL
Skyrizi	risankizumab	600mg/10 mL vials	00074-5015-01	10 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	Giant cell arteritis, PJIA, rheumatoid arthritis	Administered once every 4 weeks.	
		SJIA	Administered once every 2 weeks.	
		Cytokine release syndrome, Chimeric antigen receptor T-cell induced, severe or life-threatening disease	Administer once, then if no improvement in signs and symptoms, may give up to 3 additional doses at least 8 hours apart.	
Alymsys	bevacizumab-maly	Oncology	Administered once every 2 weeks.	
Amvuttra	vutrisiran	Polyneuropathy from hATTR amyloidosis	Administered once every 3 months.	
Avastin	bevacizumab	Choroidal neovascularization secondary to pathologic myopia, angioid streaks/pseudoxanthoma elasticum, or ocular histoplasmosis syndrome	The recommended dose is every 4 weeks administration at doses up to 2.5 mg.	
		Diabetic macular edema		
		Macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO)		
		Neovascular age-related macular degeneration		
		Neovascular glaucoma		
		Neovascularization of the iris (rubeosis iridis)		
		Proliferative diabetic retinopathy		
		Type I retinopathy of prematurity		
		Oncology		Administered once every 2 weeks.

Medication Name		Diagnosis	Maximum Frequency
Brand	Generic		
Aveed	testosterone undecanoate		The recommended dose is 750mg initially, followed by 750mg after 4 weeks, then 750mg every 10 weeks thereafter.
Bavencio	avelumab	Oncology	Administered once every 2 weeks.
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.
		Diabetic macular edema	The recommended dose is 6 mg (0.05 mL) into affected eye(s) every six weeks (approximately every 39 to 45 days) for the first 5 doses, then 6 mg every 8 to 12 weeks thereafter.
Byooviz	ranibizumab-nuna	Neovascular age-related macular degeneration	The recommended dose is 0.5 mg (0.05 ML) administered by intravitreal injection once a month (approximately 28 days). Patients may be treated with 3 monthly doses followed by less frequent dosing. Patients may also be treated with one dose every 3 months after 4 monthly doses.
		Macular edema following retinal vein occlusion (RVO)	The recommended dose is 0.5 mg (0.05 ML) administered by intravitreal injection once a month (approximately 28 days).
		Myopic choroidal neovascularization (mCNV)	The recommended dose is 0.5 mg (0.05 ML) administered by intravitreal injection once a month (approximately 28 days) for up to 3 months. Patients may be retreated if needed. Maximum of 12 doses per year per eye.
Cimerli	ranibizumab-eqrn	Myopic choroidal neovascularization (mCNV)	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.
Cimerli	ranibizumab-eqrn	Diabetic macular edema (DME)	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 (DR)	
		Macular edema following retinal vein occlusion (RVO)	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.
		Neovascular (wet) age-related macular degeneration (AMD)	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.

Medication Name		Diagnosis	Maximum Frequency
Brand	Generic		
Cimzia	certolizumab pegol	Crohn's disease	Administered initially, and at weeks 2, 4, then every 4 weeks thereafter.
		Ankylosing spondylitis, axial spondyloarthritis, plaque psoriasis (BW ≤ 90 kg), psoriatic arthritis, rheumatoid arthritis	Administered initially, and at weeks 2, 4, then every other week or every 4 weeks thereafter.
		Plaque psoriasis (BW > 90kg)	Administered every other week.
Cinqair	reslizumab	Asthma	Administered once every 4 weeks.
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, 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).
		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.
		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).
Fasenra	benralizumab	Asthma	Administered once every 4 weeks for the first 3 doses, followed by once every 8 weeks thereafter.
Fulphila	pegfilgrastim-jmdb	Oncology	Administered once every 2 weeks.
Fylnetra	pegfilgrastim-pbbk	Oncology	Administered once every 2 weeks.
Hemlibra	emicizumab-kxwh	Hemophilia A	3 mg/kg once weekly for the first 4 weeks, followed by maintenance dose of: <ul style="list-style-type: none"> <li>• 1.5 mg/kg once every week; or</li> <li>• 3 mg/kg once every 2 weeks; or</li> <li>• 6 mg/kg once every 4 weeks.</li> </ul>
Herceptin	trastuzumab	Oncology	Administered once every week.
Herzuma	trastuzumab-pkrb	Oncology	Administered once every week.
Ilaris	Canakinumab	Cryopyrin-associated periodic syndromes (CAPS)	Administered once every 8 weeks.

Medication Name		Diagnosis	Maximum Frequency
Brand	Generic		
Ilaris	canakinumab	Tumor necrosis factor receptor associated periodic syndromes (TRAPS), hyperimmunoglobulin D syndrome/mevalonate kinase deficiency (HIDS/MKD), familial Mediterranean fever (FMF), Still's disease	Administered once every 4 weeks.
		Gout flares	Administered once every 12 weeks.
Ilumya	tildrakizumab-asmn	Plaque psoriasis	Administered at weeks 0, 4, and every 12 weeks thereafter.
Imfinzi	durvalumab	Oncology	Administered once every 2 weeks.
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, noninfectious uveitis, plaque psoriasis, psoriatic arthritis, ulcerative colitis	Administered at 0, 2, and 6 weeks, then every 8 weeks thereafter.
		Sarcoidosis	Administered at week 0 and 2, then once every 4 to 6 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.
Kanjinti	trastuzumab-anns	Oncology	Administered once every week.
Keytruda	pembrolizumab	Oncology	Administered once every 3 weeks.
Krystexxa	pegloticase	Chronic gout	Administered once every 2 weeks.
Leqvio	inclisiran	Hyperlipidemia	Administered initially and 3 months later, then every 6 months thereafter.
Libtayo	cemiplimab-rwlc	Oncology	Administered once every 3 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.
		Diabetic macular edema	The recommended dose is 0.3 mg to affected eye(s) once a month (approximately every 28 days).
		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).
		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.
Mvasi	bevacizumab-awwb	Oncology	Administered once every 2 weeks.
Neulasta	pegfilgrastim	Oncology	Administered once every 2 weeks.
Nucala	mepolizumab	Asthma	Administered once every 4 weeks.

Medication Name		Diagnosis	Maximum Frequency
Brand	Generic		
		Chronic rhinosinusitis with nasal polyps	
		Eosinophilic granulomatosis with polyangiitis (EGPA)	
		Hypereosinophilic syndrome (HES)	
Nyvepria	pegfilgrastim-apgf	Oncology	Administered once every 2 weeks.
Ocrevus	ocrelizumab	Multiple sclerosis (MS)	Administered intravenously initially and 2 weeks later, then every 6 months thereafter.
Ogivri	trastuzumab-dkst	Oncology	Administered once every week.
Onpattro	patisiran	Polyneuropathy from hATTR amyloidosis	Administered once every 3 weeks.
Ontruzant	trastuzumab-dttb	Oncology	Administered once every week.
Orencia	abatacept	JIA, psoriatic arthritis, rheumatoid arthritis	Administered intravenously at 0, 2, and 4 weeks, then once every 4 weeks thereafter. Administered subcutaneously once weekly.
		Graft-versus-host disease (GVHD) prophylaxis	Administered on day before transplantation, followed by a dose on day 5, 14, and 28 after transplant.
Prolia	denosumab	Osteoporosis	Administered once every 6 months.
Qalsody	tofersen	Amyotrophic lateral sclerosis	Administered every 14 days for 3 doses, followed by 100 mg every 28 days.
Radicava	edaravone	Amyotrophic lateral sclerosis	Initial treatment cycle administered with daily dosing for 14 days, followed by a 14-day drug-free period. Subsequent treatment cycles administered with daily dosing for 10 days out of 14-day periods, followed by 14-day drug-free periods.
Rolvedon	eflapegrastim-xnst	Oncology	Administered once every 2 weeks.
Rystiggo	rozanolixizumab-noli	Myasthenia gravis	Administered once every week for 6 weeks. Subsequent treatment cycles administered based on clinical evaluation.
Simponi Aria	golimumab	Ankylosing spondylitis, juvenile idiopathic arthritis, psoriatic arthritis, rheumatoid arthritis	Administered at 0, 4, then every 8 weeks thereafter.
Skyrizi	risankizumab-rzaa	Crohn's disease	Administered intravenously (IV) initially at week 0, week 4, and week 8, then administered subcutaneously at week 12, and once every 8 weeks thereafter.
Soliris	eculizumab	aHUS, MG, NMO, PNH	Administered once weekly for 5 doses, then every 2 weeks thereafter.
Spevigo (IV)	spesolimab-sbzo (IV)	Generalized pustular psoriasis	Administered intravenously as a single 900 mg dose. If flare symptoms persist, may administer an additional intravenous 900 mg dose one week after the initial dose.

Medication Name		Diagnosis	Maximum Frequency
Brand	Generic		
Spevigo (SC)	spesolimab-sbzo (SC)	Generalized pustular psoriasis	Administered subcutaneously as a loading dose of 600 mg (four 150 mg injections), followed by 300 mg (two 150 mg injections) subcutaneously 4 weeks later and every 4 weeks thereafter.  4 weeks after treatment with intravenous Spevigo for generalized pustular psoriasis flare, subcutaneous Spevigo is initiated or reinitiated at a dose of 300 mg (two 150 mg injections) administered every 4 weeks. A loading dose is not required following treatment of a generalized pustular psoriasis flare with intravenous Spevigo.
Stelara Stelara	Ustekinumab ustekinumab	Psoriasis, psoriatic arthritis	Administered subcutaneously - initially and 4 weeks later, then every 12 weeks thereafter.
		Crohn's disease, ulcerative colitis	Administered intravenously (IV) initially one time, then subcutaneously 8 weeks after the initial IV dose, then once every 8 weeks thereafter.
Stimufend	pegfilgrastim-fpgk	Oncology	Administered once every 2 weeks.
Syfovre	pegcetacoplan	geographic atrophy (GA) secondary to age-related macular degeneration (AMD)	The recommended dose is 15 mg administered to each affected eye once every 25 to 60 days.
Tecentriq	atezolizumab	Oncology	Administered once every 2 weeks.
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.
Tezspire	tezepelumab-ekko	Asthma	Administered once every 4 weeks.
Trazimera	trastuzumab-qyyp	Oncology	Administered once every week.
Udenyca	pegfilgrastim-cbqv	Oncology	Administered once every 2 weeks.
Ultomiris	ravulizumab-cwvz	aHUS, PNH	Administered initially, week 2, then once every 4 or 8 weeks thereafter, depending on body weight.
		MG, NMOSD	Administered initially, week 2, then once every 8 weeks thereafter.



Medication Name		Diagnosis	Maximum Frequency
Brand	Generic		
Vabysmo	faricimab	Neovascular age-related macular degeneration	The recommended dose is 6 mg by intravitreal injection every 4 weeks for the first 4 doses, followed by one of the following three regimens: 1) Weeks 28 and 44; 2) Weeks 24, 36, and 48; or 3) Weeks 20, 28, 36 and 44. Although most patients require dosing every 8 weeks, some patients may need dosing every 4 weeks.
		Diabetic macular edema	The recommended dose is one of the following regimens: 1) 6 mg administered by intravitreal injection every 4 weeks for at least 4 doses, followed by extensions of up to 4 week interval increments or reductions of up to 8 week interval increments based on response; or 2) 6 mg administered every 4 weeks for the first 6 doses, followed by 6 mg dose via intravitreal injections at intervals of every 8 weeks over the next 28 weeks. Although most patients require dosing every 8 weeks, some patients may need dosing every 4 weeks.
Vegzelma	bevacizumab-adcd	Oncology	Administered once every 2 weeks.
Vyepti	eptinezumab-jjmr	Migraine	Administered once every 3 months.
Vyvgart	efgartigimod alfa-fcab	Myasthenia gravis	Administered once every week for 4 weeks. Subsequent treatment cycles administered based on clinical evaluation.
Vyvgart Hytrulo	efgartigimod alfa and hyaluronidase-qvfc		Administered once every week for 4 weeks. Subsequent treatment cycles administered based on clinical evaluation.
Xgeva	denosumab	Oncology	Administered once every 4 weeks.
		Hypercalcemia of malignancy	Administer every 4 weeks with additional doses on days 8 and 15 of the first month of therapy.
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 total serum IgE levels.
		IgE-mediated Food Allergy	Administered once every 2 or 4 weeks, depending on body weight and serum total IgE levels.
Yervoy	ipilimumab	Oncology	Administered once every 3 weeks.
Ziextenzo	pegfilgrastim-bmez	Oncology	Administered once every 2 weeks.
Zirabev	bevacizumab-bvzr	Oncology	Administered once every 2 weeks.

Requests outside of this criteria will be reviewed for medical necessity on a case-by-case basis.

## 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
C9151	Injection, pegcetacoplan, 1 mg
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
J0225	Injection, vutrisiran, 1 mg
J0517	Injection, benralizumab, 1 mg
J0638	Injection, canakinumab, 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
J1301	Injection, edaravone, 1 mg
J1303	Injection, ravulizumab-cwvz, 10 mg
J1304	Injection, tofersen, 1 mg
J1306	Injection, inclisiran, 1 mg
J1449	Injection, eflapegrastim-xnst, 0.1 mg
J1602	Injection, golimumab, 1 mg, for intravenous use
J1745	Injection, infliximab, excludes biosimilar, 10 mg
J1747	Injection, spesolimab-sbzo, 1 mg
J2182	Injection, mepolizumab, 1 mg
J2327	Injection, risankizumab-rzaa, intravenous, 1 mg
J2350	Injection, ocrelizumab, 1 mg
J2356	Injection, tezepelumab-ekko, 1 mg
J2357	Injection, omalizumab, 5 mg
J2506	Injection, pegfilgrastim, 0.5 mg
J2507	Injection, pegloticase, 1 mg
J2786	Injection, reslizumab, 1 mg
J3032	Injection, eptinezumab-jjmr, 1 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, intravenous, 1 mg
J3489	Injection, zoledronic acid, 1 mg
J7170	Injection, emicizumab-kxwh, 0.5 mg
J9022	Injection, atezolizumab, 10 mg

HCPCS Code	Description
J9023	Injection, avelumab, 10 mg
J9035	Injection, bevacizumab, 10 mg
J9119	Injection, cemiplimab-rwlc, 1 mg
J9173	Injection, durvalumab, 10 mg
J9228	Injection, ipilimumab, 1 mg
J9271	Injection, pembrolizumab, 1 mg
J9299	Injection, nivolumab, 1 mg
J9311	Injection, rituximab 10 mg and hyaluronidase
J9312	Injection, rituximab, 10 mg
J9332	Injection, efgartigimod alfa-fcab, 2 mg
J9333	Injection, rozanolixizumab-noli, 1 mg
J9334	Injection, efgartigimod alfa, 2 mg and hyaluronidase-qvfc
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 (Fulphila), biosimilar, 0.5 mg
Q5111	Injection, pegfilgrastim-cbqv (Udenyca), biosimilar, 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 (ZIEXTENZO), biosimilar, 0.5 mg
Q5121	Injection, infliximab-axxq, biosimilar, (Avsola), 10 mg
Q5122	Injection, pegfilgrastim-apgf (Nyvepria), biosimilar, 0.5 mg
Q5123	Injection, rituximab-arrx, biosimilar, (Riabni), 10 mg
Q5126	injection, bevacizumab-maly, biosimilar, (Alymsys), 10 mg
Q5127	Injection, pegfilgrastim-fpgk (Stimufend), biosimilar, 0.5 mg
Q5129	Injection, bevacizumab-adcd (Vegzelma), biosimilar, 10 mg
Q5130	Injection, pegfilgrastim-pbbk (Fylnetra), biosimilar, 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
70121-1754-01	Alymsys 100mg/4mL vial
70121-1754-07	Alymsys 100mg/4mL vial
70121-1755-01	Alymsys 400mg/16mL vial
70121-1755-07	Alymsys 400mg/16mL vial
71336-1003-01	Amvuttra 25 mg/0.5 mL PFS

National Drug Code	Description
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
44087-3535-01	Bavencio 200mg/10mL 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
59310-0610-31	Cinqair 100mg/10mL vial
00574-0821-05 00143-9750-01 00591-3221-26	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
00310-1830-30	Fasenra 30mg/mL pre-filled pen
00310-1730-30	Fasenra 30mg/mL PFS

National Drug Code	Description
00310-1745-01	Fasenra 10 mg/ 0.5 mL PFS
67457-0833-06	Fulphila 6 mg/0.6 mL PFS
70121-1627-01	Fylnetra 6mg/0.6 mL 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
63459-0305-47	Herzuma 420 mg vial
00078-0734-61	Ilaris 150mg/mL vial
47335-0177-95	Ilumya 100mg/mL PFS
00310-4500-12	Imfinzi 120 mg/2.4 mL vial
00310-4611-50	Imfinzi 500 mg/10 mL vial
00069-0809-01	Inflectra 100 mg vial
55513-0141-01	Kanjinti 150 mg vial
55513-0132-01	Kanjinti 420 mg vial
00006-3029-01 00006-3029-02	Keytruda 50 mg vial
00006-3026-01 00006-3026-02 00006-3026-04	Keytruda 100 mg/4 mL vial
75987-0080-10	Krystexxa 8mg/mL vial
00078-1000-60	Leqvio 284mg/1.5mL PFS
61755-0008-01	Libtayo 350mg/7mL 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
00173-0881-01	Nucala 100 mg vials
00173-0904-42	Nucala 40mg/0.4mL PFS
00173-0892-01	Nucala 100mg/mL PFS
00173-0892-42	Nucala 100mg/mL PFS
00069-0324-01	Nyvepria 6 mg/0.6 mL PFS
50242-0150-01	Ocrevus 300mg/10 mL vial
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
00003-3756-14	Opdivo 120mg/12 mL vials
00003-3734-13	Opdivo 240 mg/24 ml vial
00003-3772-11	Opdivo 40 mg/4 mL vial

National Drug Code	Description
00003-2187-10 00003-2187-13	Orencia 250 mg vial
55513-0710-01	Prolia 60 mg/1 mL PFS
64406-0109-01	Qalsody 100mg/15mL vial
70510-2171-01 70510-2171-02	Radicava 30mg/100mL bag
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
55513-0224-01	Riabni 100 mg/10 mL vial
55513-0326-01	Riabni 500 mg/50 mL 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
76961-0101-01	Rolvedon 13.2mg/0.6mL PFS
00069-0238-01	Ruxience 100 mg/10 mL vial
00069-0249-01	Ruxience 500 mg/50 mL vial
50474-0980-79	Rystiggo 280 mg/2 mL vial
57894-0350-01	Simponi Aria 50 mg/4 mL vial
00074-5015-01	Skyrizi 600mg/10 mL vials
25682-0001-01	Soliris 300 mg/30 mL vial
00597-0035-10	Spevigo 450mg/7.5mL vial
00597-0620-20	Spevigo 150 mg/mL PFS
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
65219-0371-10	Stimufend 6mg/0.6mL PFS
50242-0918-01	Tecentriq 840mg/14mL vial
50242-0917-01	Tecentriq 1200mg/20mL vial
66887-0004-01 66887-0004-10 66887-0004-20	Testopel 75 mg pellet
55513-0123-01	Tezspire 210mg/1.91mL pre-filled pen
55513-0112-01	Tezspire 210mg/1.91mL PFS
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
25682-0025-01	Ultomiris 300 mg/3 mL vial
25682-0028-01	Ultomiris 1,100 mg/11 mL vial

National Drug Code	Description
32228-0011-01 32228-0011-02	Vegzelma 100 mg/4 mL vial
32228-0011-03 32228-0011-04	Vegzelma 400 mg/16 mL vial
67386-0130-51	Vyepti 100 mg/mL vial
73475-3041-05	Vyvgart 400 mg/20 mL vial
73475-3102-03	Vyvgart Hytrulo 1,008 mg, 11,200 units /5.6 mL vial
55513-0730-01	Xgeva 120 mg/1.7 mL vial
50242-0040-62	Xolair 150 mg vial
50242-0214-01	Xolair 75 mg/0.5 mL PFS
50242-0215-01	Xolair 150 mg/mL PFS
50242-0214-03	Xolair 75 mg/0.5 mL PFS
50242-0215-03	Xolair 150 mg/mL PFS
50242-0227-01	Xolair 300 mg/mL PFS
50242-0214-55	Xolair 75 mg/0.5 mL autoinjector
50242-0215-55	Xolair 150 mg/mL autoinjector
50242-0227-55	Xolair 300 mg/mL autoinjector
00003-2327-11	Yervoy 50mg/10mL vials
00003-2328-22	Yervoy 200mg/40mL vials
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	Zoledronic Acid 5 mg/100 mL vial



National Drug Code	Description
55111-0688-52 63323-0966-00 67457-0619-10	Zoledronic Acid 5 mg/100 mL vial

## 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 95<sup>th</sup> percentile for adult body weight (140 kg) and body surface area (2.71 meters<sup>2</sup>) in the U.S. (adult male, 30 to 39 years, Fryar, 2021).<sup>59</sup>

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 [package insert]. South San Francisco, CA: Genentech, Inc.; February 2022.
2. Avastin [package insert]. South San Francisco, CA: Genentech, Inc.; January 2021.
3. Aveed [prescribing information]. Malvern, PA: Endo Pharmaceuticals; August 2021.
4. Avsola [prescribing information]. Thousand Oaks, CA: Amgen, Inc.; September 2021.
5. Beovu® [prescribing information]. East Hanover, NJ; Novartis Pharmaceuticals Corporation; May 2022.
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]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; June 2022.
9. Eylea® [prescribing information]. Tarrytown, NY; Regeneron Pharmaceuticals, Inc.; June 2021.
10. Fulphila [prescribing information]. Rockford, IL: Mylan Institutional, LLC, October 2021.
11. Hemlibra [prescribing information]. South San Francisco, CA: Genentech, Inc.; June 2022.
12. Herceptin [package insert]. South San Francisco, CA: Genentech, Inc.; February 2021.
13. Herzuma [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; May 2019.
14. Ilumya [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; July 2020.
15. Inflectra [prescribing information]. New York, NY: Pfizer Labs; March 2022.
16. Kanjinti [package insert]. Thousand Oaks, CA: Amgen Inc.; October 2019.
17. Lucentis® [prescribing information]. South San Francisco, CA; Genentech, Inc.; March 2018.
18. Macugen® [prescribing information]. San Dimas, CA; Gilead Sciences, Inc.; July 2016.
19. Mvasi [package insert]. Thousand Oaks CA: Amgen Inc.; November 2021.
20. Neulasta [prescribing information]. Thousand Oaks, CA: Amgen Inc.; February 2021.
21. Nyvepria [prescribing information]. Lake Forest, IL: Pfizer Oncology; October 2021.
22. Ogivri [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; February 2021.
23. Onpattro [prescribing information]. Cambridge, MA: Alnylam Pharmaceuticals, Inc.; July 2022.
24. Ontruzant [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; June 2021.

25. Orenicia [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Co.; December 2021.
26. Opdivo [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company, May 2022.
27. Prolia [prescribing information]. Thousand Oaks, CA: Amgen Inc.; May 2022.
28. Reclast [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2017.
29. Remicade [prescribing information]. Horsham, PA: Janssen Biotech Inc.; October 2021.
30. Renflexis [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; January 2022.
31. Rituxan [prescribing information]. South San Francisco, CA: Genentech, Inc.; December 2021.
32. Rituxan Hycela [prescribing information]. South San Francisco, CA: Genentech, Inc.; June 2021.
33. Ruxience [prescribing information]. New York, NY: Pfizer Labs; November 2021.
34. Simponi Aria [prescribing information]. Horsham, PA: Janssen Biotech, Inc.; February 2021.
35. Soliris [prescribing information]. Boston, MA: Alexion Pharmaceuticals, Inc.; November 2020.
36. Stelara [prescribing information]. Horsham, PA: Janssen Biotech, Inc. August 2022.
37. Testopel [prescribing information]. Malvern, PA: Endo Pharmaceuticals, Inc.; August 2018.
38. Trazimera [package insert]. New York, NY: Pfizer Inc.; November 2020.
39. Truxima [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; February 2022.
40. Udenyca [prescribing information]. Redwood City, CA: Coherus BioSciences, Inc, June 2021.
41. Ultomiris [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; March 2024.
42. Xgeva [package insert]. Thousand Oaks, CA: Amgen Inc.; June 2020.
43. Xolair [prescribing information]. South San Francisco, CA: Genentech, Inc., February 2024.
44. Ziextenzo [prescribing information]. Princeton, NJ: Sandoz, Inc.; March 2021.
45. Zirabev [package insert]. New York, NY: Pfizer Inc.; May 2021.
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.
51. Bavencio [package insert]. Rockland, MA: EMD Serono, Inc.; November 2020.
52. Imfinzi [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2021.
53. Keytruda [package insert]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp.; March 2022.
54. Libtayo [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; February 2021.
55. Tecentriq [package insert]. South San Francisco, CA: Genentech, Inc.; January 2022.
56. Yervoy [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; February 2022.
57. Riabni [package insert]. Thousand Oaks, CA: Amgen, Inc.; December 2020.
58. Alymsys [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; April 2022.
59. Fryar CD, Carroll MD, Gu Q, Afful J, Ogden CL. Anthropometric reference data for children and adults: United States, 2015–2018. *National Center for Health Statistics. Vital Health Stat* 3(46). 2021.
60. Byooviz (ranibizumab-nuna injection) [package insert]. Cambridge, MA: Biogen, Inc; 2022 Jun.
61. Cimerli (ranibizumab-eqrn injection) [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; November 2022.
62. Amvuttra [prescribing information]. Cambridge, MA: Alnylam Pharmaceuticals, Inc.; June 2022.
63. Skyrizi [prescribing information]. North Chicago, IL: AbbVie Inc.; September 2022.

64. Vegzelma [package insert]. Jersey City, NJ: Celltrion USA, Inc.; February 2023.
65. Rolvedon [package insert]. Irvine, CA: Spectrum Pharmaceuticals, Inc.; September 2022.
66. Spevigo [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; March 2024.
67. Stimufend [package insert]. Lake Zurich, Illinois: Fresenius Kabi USA, LLC; September 2022.
68. Fylnetra [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; May 2022.
69. Syfovre [package insert]. Waltham, MA: Apellis Pharmaceuticals, Inc.; February 2023.
70. Tezspire [package insert]. Thousand Oaks, CA: Amgen Inc.; February 2023.
71. Cinqair [package insert]. West Chester, PA: Teva Respiratory, LLC; February 2020.
72. Fasenra [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; April 2024.
73. Nucala [package insert]. Philadelphia, PA: GlaxoSmithKline LLC; March 2023.
74. Ocrevus [package insert]. South San Francisco, CA: Genentech, Inc.; March 2023.
75. Krystexxa [package insert]. Deerfield, IL: Horizon Therapeutics USA, Inc.; November 2022.
76. Ilaris [package insert]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation; August 2023.
77. Qalsody [package insert]. Cambridge, MA: Biogen MA Inc.; April 2023.
78. Vyvgart [package insert]. Boston, MA: argenx US, Inc.; December 2023.
79. Vyvgart Hytrulo [package insert]. Boston, MA: argenx US, Inc.; December 2023.
80. Rystiggo [package insert]. Smyrna, GA: UCB, Inc.; June 2023.
81. Vyepti [package insert]. Bothell, WA: Lundbeck Seattle BioPharmaceuticals, Inc.; October 2022.
82. Radicava [package insert]. Jersey City, NJ: Mitsubishi Tanabe Pharma America, Inc.; November 2022.
83. Leqvio [package insert]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation; July 2023.

## Policy History/Revision Information

Date	Summary of Changes
09/01/2024	<p><b>Coverage Rationale</b></p> <p><b>Maximum Allowed Quantities for National Drug Code (NDC) Billing</b></p> <ul style="list-style-type: none"> <li>● Revised list of NDCs with maximum allowed quantities; added: <ul style="list-style-type: none"> <li>○ Fasenra (benralizumab): NDC 00310-1745-01</li> <li>○ Spevigo (spesolimab-sbzo): NDC 00597-0620-20</li> <li>○ Xolair (omalizumab): <ul style="list-style-type: none"> <li>▪ NDC 50242-0214-03</li> <li>▪ NDC 50242-0215-03</li> </ul> </li> </ul> </li> </ul> <p><b>Maximum Allowed Frequencies</b></p> <ul style="list-style-type: none"> <li>● Revised list of drug products with maximum allowed frequencies; added: <ul style="list-style-type: none"> <li>○ Spevigo (spesolimab-sbzo) (SC) for the diagnosis of generalized pustular psoriasis: <ul style="list-style-type: none"> <li>▪ Administered subcutaneously as a loading dose of 600 mg (four 150 mg injections), followed by 300 mg (two 150 mg injections) subcutaneously 4 weeks later and every 4 weeks thereafter</li> <li>▪ 4 weeks after treatment with intravenous Spevigo for generalized pustular psoriasis flare, subcutaneous Spevigo is initiated or reinitiated at a dose of 300 mg (two 150 mg injections) administered every 4 weeks; a loading dose is not required following treatment of a generalized pustular psoriasis flare with intravenous Spevigo</li> </ul> </li> <li>○ Ultomiris (ravulizumab-cwvz) for the diagnosis of neuromyelitis optica spectrum disorder (NMOSD): <ul style="list-style-type: none"> <li>▪ Administered initially, week 2, then once every 8 weeks thereafter</li> </ul> </li> </ul> </li> </ul> <p><b>Applicable Codes</b></p> <ul style="list-style-type: none"> <li>● Added NDCs 00310-1745-01, 00597-0620-20, 50242-0040-62, 50242-0214-03, 50242-0214-55, 50242-0215-03, 50242-0215-55, 50242-0227-01, and 50242-0227-55</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>● Updated <i>References</i> section to reflect the most current information</li> </ul>

Date	Summary of Changes
	<ul style="list-style-type: none"> <li>Archived previous policy version CSPA2024D0034AK</li> </ul>

## 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<sup>®</sup> 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.