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MAXIMUM DOSAGE & FREQUENCY

Policy Number: CSLA2020D0034X

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Related Community Plan Policies

- [Cimzia® \(Certolizumab Pegol\)](#)
- [Complement Inhibitors \(Soliris® & Ultomiris™\)](#)
- [Denosumab \(Prolia® & Xgeva®\)](#)
- [Entyvio® \(Vedolizumab\)](#)
- [Infliximab \(Remicade®, Inflectra™, Renflexis™\)](#)
- [Oncology Medication Clinical Coverage](#)
- [Onpattro™ \(Patisiran\)](#)
- [Ophthalmologic Policy: Vascular Endothelial Growth Factor \(VEGF\) Inhibitors](#)
- [Rituximab \(Rituxan®, Ruxience™, & Truxima®\)](#)
- [Stelara® \(Ustekinumab\)](#)
- [White Blood Cell Colony Stimulating Factors](#)
- [Xolair® \(Omalizumab\)](#)

Commercial Policy

- [Maximum Dosage](#)

APPLICATION

This Medical Benefit Drug Policy only applies to state of Louisiana.

COVERAGE RATIONALE

This policy provides information about the maximum dosage per administration for certain medications administered by a medical professional. Most medications have a maximum dosage based upon body surface area or patient weight or a set maximal dosage 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 \(Rituxan Hycela®\)](#)**

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- 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®)

DRAFT

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 meters²) 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 meters².

Maximum Allowed Quantities by HCPCs Units

Medication Name		Diagnosis	Maximum Dosage per Administration	HCPCs Code	Maximum Allowed
Brand	Generic				
<u>Actemra</u>	<u>tocilizumab</u>		<u>800 mg</u>	<u>J3262</u>	<u>800 HCPCs units (1 mg per unit)</u>
Avastin Mvasi Zirabev	bevacizumab bevacizumab- awwb bevacizumab-bvzr		15 mg/kg 15 mg/kg 15 mg/kg	J9035	192 HCPCs units (10 mg per unit)
				Q5107	192 HCPCs units (10 mg per unit)
				Q5118	192 HCPCs units (10 mg per unit)
<u>Aveed</u>	<u>testosterone undecanoate</u>		<u>750mg</u>	<u>J3145</u>	<u>750 HCPCs units (1 mg per unit)</u>
Cimzia	certolizumab pegol		400 mg total dose	J0717	400 HCPCs units (1 mg per unit)
<u>Delatestryl</u>	<u>testosterone enanthate</u>		<u>400 mg</u>	<u>J3121</u>	<u>400 HCPCs units (1 mg per unit)</u>
<u>Depo-Testosterone</u>	<u>testosterone cypionate</u>		<u>400 mg</u>	<u>J1071</u>	<u>400 HCPCs units (1 mg per unit)</u>
Entyvio	vedolizumab		300 mg	J3380	300 HCPCs units (1 mg per unit)
<u>Hemlibra</u>	<u>Emicizumab-kxwh</u>		<u>6 mg/kg</u>	<u>J7170</u>	<u>1,536 HCPCs units (0.5 mg per unit)</u>
Herceptin Herzuma Kanjinti Ogivri Ontruzant Trazimera	trastuzumab trastuzumab-pkrb trastuzumab-anns trastuzumab-dkst trastuzumab-dttb trastuzumab-qyyp		8 mg/kg 8 mg/kg 8 mg/kg 8 mg/kg 8 mg/kg 8 mg/kg	J9355	103 HCPCs units (10 mg per unit)
				Q5113	103 HCPCs units (10 mg per unit)
				Q5117	103 HCPCs units (10 mg per unit)
				Q5114	103 HCPCs units (10 mg per unit)
				Q5112	103 HCPCs units (10 mg per unit)
				Q5116	103 HCPCs units (10 mg per unit)
					103 HCPCs units (10 mg per unit)

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Medication Name		Diagnosis	Maximum Dosage per Administration	HCPCs Code	Maximum Allowed
Brand	Generic				
<u>Ilumya</u>	<u>tildrakizumab-asmn</u>		<u>100 mg</u>	<u>J3245</u>	<u>100 HCPCs units (1 mg per unit)</u>
Neulasta	pegfilgrastim		6 mg total dose	J2505	1 HCPCs unit (6 mg per unit)
Fulphila Udenyca <u>Ziextenzo</u>	pegfilgrastim-jmdb pegfilgrastim-cbqv <u>pegfilgrastim-bmez</u>		6 mg total dose 6 mg total dose	Q5108 Q5111 <u>TBD</u>	12 HCPCs units (0.5mg per unit) 12 HCPCs units (0.5mg per unit)
Opdivo	nivolumab		480 mg	J9299	480 HCPCs units (1 mg per unit)
<u>Orencia</u>	<u>Abatacept</u>		<u>1000 mg</u>	<u>J0129</u>	<u>100 HCPCs units (10 mg per unit)</u>
Reclast	zoledronic acid		5 mg total dose	J3489	5 HCPCs units (1 mg per unit)
zoledronic acid			5 mg total dose		
			4 mg total dose		
Zometa			4 mg total dose		
Remicade <u>Avsola</u>	infliximab <u>infliximab-axxq</u>		10 mg/kg 10 mg/kg	J1745 <u>TBD</u>	128 HCPCs units (10 mg per unit)
Renflexis Inflectra	infliximab-abda infliximab-dyyb		10 mg/kg	Q5104 Q5103	128 HCPCs units (10 mg per unit) 128 HCPCs units (10 mg per unit)
Onpattro	patisiran		30 mg total dose	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 <u>Ruxience</u> Truxima	rituximab <u>rituximab-pvvr</u> rituximab-abbs		1,225 mg total dose 1,225 mg total dose	J9312 <u>TBD</u> Q5115	123 HCPCs units (10 mg per unit) 123 HCPCs units (10 mg per unit)
<u>Rituxan Hycela</u>	<u>rituximab and hyaluronidase</u>		<u>1,600 mg</u>	<u>J9311</u>	<u>160 HCPCs units (10 mg per unit)</u>
<u>Simponi Aria</u>	<u>golimumab</u>		<u>2 mg/kg</u>	<u>J1602</u>	<u>256 HCPCs units (1 mg per unit)</u>
Soliris	eculizumab	PNH	900 mg	J1300	90 HCPCs units (10 mg per unit)
		aHUS, MG, NMOsD	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)

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Medication Name		Diagnosis	Maximum Dosage per Administration	HCPCs Code	Maximum Allowed
Brand	Generic				
<u>Testopel</u>	<u>testosterone pellet</u>		<u>450 mg</u>	<u>S0189</u>	<u>6 HCPCs units (75 mg per unit)</u>
Ultomiris	ravulizumab-cwvz		3,600 mg total dose	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)

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				
<u>Actemra</u>	<u>Tocilizumab</u>		<u>20 mg/mL vials</u>	<u>50242-0135-01</u> <u>50242-0136-01</u> <u>50242-0137-01</u>	<u>40 mL</u>
Avastin	bevacizumab		100 mg/4 mL solution in vials	50242-0060-01 <u>50242-0060-10</u>	77 mL
			400 mg/16 mL solution in vials	50242-0061-01 <u>50242-0061-10</u>	77 mL
Mvasi	bevacizumab-awwb		100 mg/4 mL solution in vials	55513-0206-01	77 mL
			400 mg/16 mL solution in vials	55513-0207-01	77 mL
Zirabev	bevacizumab-bvzr		100 mg/4 mL solution in vials	00069-0315-01	77 mL
			400 mg/16 mL solution in vials	00069-0342-01	77 mL
<u>Aveed</u>	<u>testosterone undecanoate</u>		<u>750 mg/3 mL</u>	<u>67979-0511-43</u>	<u>3 mL</u>
Cimzia	Certolizumab pegol		2 x 200mg kit	50474-0700-62	2 vials
			2 x 200mg/ml prefilled syringe (PFS) kit	50474-0710-79	2 mL
			6 x 200 mg/ml prefilled syringe <u>PFS</u> kit	50474-0710-81	2 mL
<u>Delatestryl</u>	<u>testosterone enanthate</u>		<u>200 mg/mL</u>	<u>00134-9750-01</u>	<u>2 mL</u>
<u>Depo-Testosterone</u>	<u>testosterone cypionate</u>		<u>200 mg/mL</u>	<u>00517-1830-01</u> <u>52536-0625-10</u>	<u>2 mL</u>

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Medication Name		Diagnosis	How Supplied	National Drug Code	Maximum Allowed
Brand	Generic				
				<u>52536-0625-01</u>	
				<u>64980-0467-99</u>	
				<u>69097-0802-32</u>	
				<u>69097-0802-37</u>	
				<u>00574-0827-01</u>	
				<u>76519-1210-00</u>	
				<u>00009-0086-01</u>	
				<u>00009-0417-01</u>	
				<u>00009-0520-01</u>	
				<u>69097-0536-37</u>	
				<u>69097-0537-31</u>	
				<u>69097-0537-37</u>	
				<u>50090-0330-00</u>	
				<u>00409-6562-02</u>	
				<u>00409-6562-22</u>	
				<u>00143-9659-01</u>	
				<u>62756-0017-40</u>	
				<u>62756-0016-40</u>	
				<u>00409-6557-01</u>	
				<u>00409-6562-01</u>	
				<u>00409-6562-20</u>	
				<u>76420-0650-01</u>	
				<u>00591-4128-79</u>	
				<u>00009-0085-10</u>	
				<u>00009-0086-10</u>	

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Medication Name		Diagnosis	How Supplied	National Drug Code	Maximum Allowed
Brand	Generic				
				<u>00574-0827-10</u> <u>00009-0520-10</u> <u>00009-0347-02</u> <u>62756-0015-40</u> <u>00143-9726-01</u> <u>00009-0417-02</u> <u>63874-1061-01</u> <u>00574-0820-01</u> <u>00574-0820-10</u>	
Entyvio	vedolizumab		300 mg powder for reconstitution vial vials	64764-0300-20	1 Vial
Hemlibra	<u>emicizumab-kxwh</u>		<u>30 mg/mL</u>	<u>50242-0920-01</u>	<u>768 mg</u>
			<u>105 mg/0.7 mL</u>	<u>50242-0922-01</u>	
			<u>150 mg/mL</u>	<u>50242-0923-01</u>	
			<u>60 mg/0.4 mL</u>	<u>50242-0921-01</u>	
Herceptin	trastuzumab		420 mg powder for reconstitution vial vial	50242-0333-01	3 vials
			150 mg vials powder for reconstitution vial vial	50242-0132-01	3-7 vials
Herzuma	trastuzumab-pkrb		420 mg vials powder for reconstitution vial vial	63459-0305-47	3 vials
			150 mg vials powder for reconstitution vial vial	63459-0303-43	3 vials
Kanjinti	trastuzumab-anns		420 mg vials powder for reconstitution vial vial	55513-0132-01	3 vials
			150 mg vials powder for reconstitution vial vial	<u>55513-0141-01</u>	3 vials
Ogivri	trastuzumab-dkst		420 mg vials powder for reconstitution vial vial	67457-0847-44	3 vials
			150 mg vials powder for reconstitution vial vial	<u>67457-0845-50</u>	3 vials
Ontruzant	trastuzumab-dttb		420 mg powder for reconstitution vial vial	00006-5033-02	3 vials 3 vials

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Medication Name		Diagnosis	How Supplied	National Drug Code	Maximum Allowed
Brand	Generic				
			150 mg vials powder for reconstitution vial		
Trazimera	trastuzumab-qyyp		420 mg vials powder for reconstitution vial 150 mg powder for reconstitution vial	00069-0305-01 00069-0306-01	3 vials 3 vials
<u>Ilumya</u>	<u>tildrakizumab-asmn</u>		<u>100 mg/mL PFS</u>	<u>47335-0177-96</u> <u>47335-0177-95</u>	<u>1 mL</u>
Neulasta	pegfilgrastim		6 mg/0.6 mL prefilled syringe PFS	54868-5229-00 55513-0190-01	0.6 mL 0.6 mL
			6 mg/0.6 mL prefilled syringe PFS with on-body Injector	55513-0190 0192 -01	0.6 mL
Fulphila	pegfilgrastim-jmdb		6 mg/0.6 mL prefilled syringe PFS	67457-0833-06	0.6 mL
Udenyca	pegfilgrastim-cbqv		6 mg/0.6 mL prefilled syringe PFS	70114-0101-01	0.6 mL
<u>Ziextenzo</u>	<u>pegfilgrastim-bmez</u>		<u>6 mg/0.6 mL PFS</u>	<u>61314-0866-01</u>	<u>0.6 mL</u>
Opdivo	nivolumab		100 mg/10 mL solution in vials	00003-3774-12	40 mL
			240 mg/24 mL solution in vials	00003-3734-13	48 mL
			40 mg/4 mL solution in vials	00003-3772-11	8 mL
Onpattro	patisiran		10 mg/5 mL solution in vials	71336-1000-01	15 mL
<u>Orencia</u>	<u>abatacept</u>		<u>250 mg vials</u>	<u>00003-2187-10</u> <u>00003-2187-13</u>	<u>4 vials</u>
Remicade	infliximab		100 mg vials powder for reconstitution vial	57894-0030-01	13 vials
<u>Avsola</u>	<u>infliximab-axxq</u>		<u>100 mg vials</u>	<u>55513-0670-01</u>	<u>13 vials</u>
Renflexis	infliximab-abda		100 mg vials powder for reconstitution vial	<u>00006-4305-01</u> 00006-4305-02	13 vials
Inflectra	infliximab-dyyb		100 mg vials powder for reconstitution vial	32228-0001-01 <u>00069-0809-01</u>	13 vials
Rituxan	rituximab		100 mg/10 mL solution in vials	<u>50242-0051-10</u> 50242-0051-21	40 mL
			500 mg/50 mL solution in vials	50242-0053-06	130 mL

Medication Name		Diagnosis	How Supplied	National Drug Code	Maximum Allowed
Brand	Generic				
<u>Ruxience</u>	<u>rituximab-pvvr</u>		<u>100 mg/10 mL vials</u>	<u>00069-0238-01</u>	<u>40 mL</u>
			<u>500 mg/50 mL vials</u>	<u>00069-0249-01</u>	<u>130 mL</u>
Truxima	rituximab-abbs		100 mg/10 mL solution in vials	63459-0103-10	40 mL
			500 mg/50 mL solution in vials	63459-0104-50	130 mL
<u>Rituxan Hycela</u>	<u>rituximab and hyaluronidase</u>		<u>1,400-23,400 mg/11.7 mL</u>	<u>50242-0108-01</u>	<u>1 vial</u>
			<u>1,600-26,800 mg/13.4 mL</u>	<u>50242-0109-01</u>	<u>1 vial</u>
<u>Simponi Aria</u>	<u>golimumab</u>		<u>50 mg/4 mL</u>	<u>57894-0350-01</u>	<u>21 mL</u>
Soliris	eculizumab	PNH	300 mg/30 mL solution in vials	25682-0001-01	90 mL
		aHUS, MG	300 mg/30 mL solution in vials	25682-0001-01	120 mL
Stelara	ustekinumab		45 mg/0.5 mL prefilled syringe <u>PFS</u>	57894-0060-03	0.5 mL
			45 mg/0.5 mL solution in vials	57894-0060-02	0.5 mL
			90 mg/1 mL prefilled syringe <u>PFS</u>	57894-0061-03	1 mL
		Crohn's Disease <u>Ulcerative colitis</u>	130 mg/26 mL solution in vials	57894-0054-27	104 mL
<u>Testopel</u>	<u>testosterone pellet</u>		<u>75 mg pellet</u>	<u>66887-0004-01</u> <u>66887-0004-10</u> <u>66887-0004-20</u>	<u>6 pellets</u>
Ultomiris	ravulizumab-cwvz		300 mg/30 mL solution in vials	25682-0022-01	360 mL
Xolair	omalizumab	Asthma	150 mg vials powder for reconstitution <u>vial</u>	50242-0040-62	2 vials
			150 mg prefilled syringe <u>PFS</u>	50242-0215-01 <u>50242-0215-86</u>	2 mL
			75 mg prefilled syringe <u>PFS</u>	50242-0214-01	1 mL
		Chronic Urticaria	150 mg vials powder for reconstitution <u>vial</u>	50242-0040- 62 <u>86</u>	2 vials
150 mg prefilled syringe <u>PFS</u>	50242-0215-01 <u>50242-0215-86</u>		2 mL		

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Medication Name		Diagnosis	How Supplied	National Drug Code	Maximum Allowed
Brand	Generic				
			75 mg prefilled syringe PFS	50242-0214-01	1 mL
Prolia	denosumab	Osteoporosis	60 mg/1 mL prefilled syringe PFS	55513-0710-01	1 mL
Xgeva	denosumab	Oncology	120 mg/1.7 mL solution in vials	55513-0730-01	1.7 mL
Reclast Zometa zoledronic acid zoledronic acid zoledronic acid zoledronic acid	zoledronic acid zoledronic acid zoledronic acid zoledronic acid zoledronic acid		4 mg/5 mL solution in vials	00409-4215-01 00409-4215-05 00078-0387-25 00143-9642-01 16714-0815-01 16729-0242-31 23155-0170-31 47335-0035-40 25021-0801-66 42023-0151-01 43598-0330-11 53150-0871-01 60505-6110-00 45963-0440-55 47335-0962-41 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 solution in vials	00078-0590-61 70860-0210-51	100 mL

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Medication Name		Diagnosis	How Supplied	National Drug Code	Maximum Allowed
Brand	Generic				
			<u>4 mg/100 mL infusion</u>	00078-0435-61 <u>00409-4229-01</u> 23155-0186-31 <u>25021-0826-67</u> 25021-0826-82	<u>100 mL</u>
			5 mg/100 mL solution in vials	<u>00078-0435-61</u> 35356-0351-01 25021-0830-82 2023-0163-01 43598-0331-11 <u>51991-0064-98</u> 55111-0688-52 <u>63323-0966-00</u> <u>67457-0619-10</u>	100 mL 100 mL
			<u>5 mg/100 mL infusion</u>	<u>00409-4228-01</u> <u>25021-0830-82</u> <u>67457-0794-10</u> <u>70860-0802-82</u>	<u>100 mL</u>

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		
<u>Actemra</u>	<u>tocilizumab</u>	<u>PJIA</u> <u>Rheumatoid Arthritis</u>	<u>Administered once every 4 weeks</u>
		<u>SJIA</u>	<u>Administered once every 2 weeks</u>
<u>Aveed</u>	<u>testosterone undecanoate</u>		<u>The recommended dose is 750mg initially, followed by 750mg after 4 weeks, then 750mg every 10 weeks thereafter.</u>
<u>Cimzia</u>	<u>certolizumab pegol</u>	<u>Crohn's Disease</u>	<u>Administered initially, and at weeks 2, 4, then every 4 weeks thereafter</u>

Medication Name		Diagnosis	Maximum Frequency
Brand	Generic		
		<u>Ankylosing Spondylitis</u> <u>Axial Spondyloarthritis</u> <u>Plaque Psoriasis (BW ≤ 90kg)</u> <u>Psoriatic Arthritis</u> <u>Rheumatoid Arthritis</u>	<u>Administered initially, and at weeks 2, 4, then every other /every 2 weeks thereafter.</u>
		<u>Plaque Psoriasis (BW > 90kg)</u>	<u>Administered every other week</u>
<u>Delatestryl</u>	<u>testosterone enanthate</u>		<u>For replacement therapy, 50 mg to 400 mg every 2 to 4 weeks, not to exceed 400 mg per month</u>
<u>Depo-testosterone</u>	<u>testosterone cypionate</u>		<u>For replacement in the hypogonadal male, 50 mg to 400 mg every 2 to 4 weeks, not to exceed 400 mg per month</u>
<u>Entyvio</u>	<u>vedolizumab</u>	<u>Crohn's Disease</u> <u>Ulcerative Colitis</u>	<u>Administered at 0, 2, and 6 weeks, then every 8 weeks thereafter</u>
<u>Hemlibra</u>	<u>emicizumab-kxwh</u>		<u>3 mg/kg once weekly for the first 4 weeks, followed by maintenance dose of:</u> <ul style="list-style-type: none"> • <u>1.5 mg/kg once every week; or</u> • <u>3 mg/kg once every 2 weeks; or</u> • <u>6 mg/kg once every 4 weeks</u>
<u>Ilumya</u>	<u>tildrakizumab-asmn</u>	<u>Plaque Psoriasis</u>	<u>Administered at weeks 0, 4, and every 12 weeks thereafter</u>
<u>Remicade</u> <u>Avsola</u> <u>Inflectra</u> <u>Renflexis</u>	<u>infliximab</u> <u>infliximab-axxg</u> <u>infliximab-dyyb</u> <u>infliximab-abda</u>	<u>Ankylosing Spondylitis</u>	<u>Administered at 0, 2, and 6 weeks, then every 6 weeks thereafter</u>
		<u>Crohn's Disease</u> <u>Noninfectious uveitis</u> <u>Plaque Psoriasis</u> <u>Psoriatic Arthritis</u> <u>Sarcoidosis</u> <u>Ulcerative Colitis</u>	<u>Administered at 0, 2, and 6 weeks, then every 8 weeks thereafter</u>
		<u>Rheumatoid Arthritis</u>	<u>Administered at 0, 2, and 6 weeks, then every 8 weeks thereafter. Maintenance treatment may be increased to as often as every 4 weeks.</u>
<u>Onpattro</u>	<u>patisiran</u>	<u>Polyneuropathy from hATTR amyloidosis</u>	<u>Administered once every 3 weeks</u>
<u>Orencia</u>	<u>abatacept</u>	<u>JIA</u> <u>Rheumatoid Arthritis</u> <u>Psoriatic Arthritis</u>	<u>Administered at 0, 2, and 4 weeks, then once every 4 weeks thereafter.</u>

Medication Name		Diagnosis	Maximum Frequency
Brand	Generic		
<u>Prolia</u>	<u>denosumab</u>	<u>Osteoporosis</u>	<u>Administered once every 6 months</u>
<u>Simponi Aria</u>	<u>golimumab</u>	<u>Ankylosing Spondylitis</u> <u>Psoriatic Arthritis</u> <u>Rheumatoid Arthritis</u>	<u>Administered at 0, 4, then every 8 weeks thereafter</u>
<u>Soliris</u>	<u>eculizumab</u>	<u>PNH, aHUS, MG, NMOSD</u>	<u>Administered once weekly for 5 doses, then every 2 weeks thereafter</u>
<u>Stelara</u>	<u>ustekinumab</u>	<u>Psoriasis</u> <u>Psoriatic arthritis</u>	<u>Administered subcutaneously - initially and 4 weeks later, then every 12 weeks thereafter</u>
		<u>Crohn's Disease</u> <u>Ulcerative colitis</u>	<u>Administered intravenously (IV) initially one time, then subcutaneously 8 weeks after the initial IV dose, then once every 8 weeks thereafter</u>
<u>Testopel</u>	<u>testosterone pellet</u>		<u>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.</u>
<u>Ultomiris</u>	<u>ravulizumab-cwvz</u>	<u>PNH</u>	<u>Administered initially, week 2, then once every 8 weeks thereafter</u>
		<u>aHUS</u>	<u>Administered initially, week 2, then once every 4 or 8 weeks thereafter, depending on body weight</u>
<u>Xgeva</u>	<u>denosumab</u>	<u>Oncology</u>	<u>Administered once every 4 weeks</u>
<u>Xolair</u>	<u>omalizumab</u>	<u>Asthma</u>	<u>Administered once every 2 or 4 weeks, depending on body weight and igE levels</u>
		<u>Chronic Urticaria</u>	<u>Administered once every 4 weeks</u>

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 Coverage Determination Guidelines may apply.

HCPCS Code	Description
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)

HCPSC Code	Description
J0897	Injection, denosumab, 1 mg
J1300	Injection, eculizumab, 10 mg
J1303	Injection, ravulizumab-cwvz, 10 mg
J1745	Injection, infliximab, excludes biosimilar, 10 mg
J2357	Injection, omalizumab, 5 mg
J2505	Injection, pegfilgrastim, 6 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
J9035	Injection, bevacizumab, 10 mg
J9299	Injection, nivolumab, 1 mg
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, (udenycya), 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

National Drug Code	Description
50242-0060-01	Avastin 100 mg/4 mL solution in vials
50242-0061-01	Avastin 400 mg/16 mL solution in vials
50474-0700-62	Cimzia 2 x 200mg kit
50474-0710-79	Cimzia 2 x 200mg/ml prefilled syringe kit
50474-0710-81	Cimzia 6 x 200 mg/ml prefilled syringe kit
64764-0300-20	Entyvio 300 mg powder for reconstitution
67457-0833-06	Fulphila 6 mg/0.6ml prefilled syringe
50242-0333-01	Herceptin 420 mg powder for reconstitution
50242-0132-01	Herceptin 150 mg powder for reconstitution
63459-0305-47	Herzuma 420 mg powder for reconstitution
63459-0303-43	Herzuma 150 mg powder for reconstitution
32228-0001-01	Inflectra 100 mg powder for reconstitution
55513-0132-01	Kanjinti 420 mg powder for reconstitution
55513-0190-01	Neulasta 6 mg/0.6 mL prefilled syringe

National Drug Code	Description
54868-5229-00	Neulasta 6 mg/0.6 mL prefilled syringe
55513-0206-01	Mvasi 100 mg/4 mL solution in vials
55513-0207-01	Mvasi 400 mg/16 mL solution in vials
67457-0847-44	Ogivri 420 mg powder for reconstitution
67457-0991-15	Ogivri 150 mg powder for reconstitution
	Ontruzant 420 mg powder for reconstitution
00006-5033-02	Ontruzant 150 mg powder for reconstitution
00003-3774-12	Opdivo 100 mg/10 ml solution in vials
00003-3734-13	Opdivo 240 mg/24 ml solution in vials
00003-3772-11	Opdivo 40 mg/4 mL solution in vials
71336-1000-01	Onpattro 10 mg/5 mL solution in vials
55513-0710-01	Prolia 60 mg/1 mL prefilled syringe
00078-0435-61	Reclast 5 mg/100 mL solution in vials
35356-0351-01	Reclast 5 mg/100 mL solution in vials
57894-0030-01	Remicade 100 mg powder for reconstitution
00006-4305-02	Renflexis 100 mg powder for reconstitution
50242-0051-21	Rituxan 100 mg/10 mL solution in vials
50242-0053-06	Rituxan 500 mg/50 mL solution in vials
25682-0001-01	Soliris 300 mg/30 mL solution in vials
57894-0060-03	Stelara 45 mg/0.5 mL prefilled syringe
57894-0060-02	Stelara 45 mg/0.5 mL solution in vials
57894-0061-03	Stelara 90 mg/1 mL prefilled syringe
57894-0054-27	Stelara 130 mg/26 mL solution in vials
00069-0305-01	Trazimera 420 mg powder for reconstitution
	Trazimera 150 mg powder for reconstitution
63459-0103-10	Truxima 100 mg/10 mL solution in vials
63459-0104-50	Truxima 500 mg/50 mL solution in vials
70114-0101-01	Udenyca 6 mg/0.6 mL prefilled syringe
25682-0022-01	Ultomiris 300 mg/30 mL solution in vials
55513-0730-01	Xgeva 120 mg/1.7 mL solution in vials
50242-0040-62	Xolair 150 mg powder for reconstitution
50242-0214-01	Xolair 75 mg prefilled syringe
50242-0215-01	Xolair 150 mg prefilled syringe
00069-0315-01	Zirabev 100 mg/4 mL solution in vials
00069-0342-01	Zirabev 400 mg/16 mL solution in vials
25021-0830-82	Zoledronic Acid 5 mg/100 mL solution in vials
42023-0163-01	Zoledronic Acid 5 mg/100 mL solution in vials
43598-0331-11	Zoledronic Acid 5 mg/100 mL solution in vials
23155-0186-31	Zoledronic Acid 5 mg/100 mL solution in vials
55111-0688-52	Zoledronic Acid 5 mg/100 mL solution in vials
00143-9642-01	Zoledronic Acid 4 mg/5 mL solution in vials
47335-0035-40	Zoledronic Acid 4 mg/5 mL solution in vials

National Drug Code	Description
25021-0801-66	Zoledronic Acid 4 mg/5 mL solution in vials
42023-0151-01	Zoledronic Acid 4 mg/5 mL solution in vials
43598-0330-11	Zoledronic Acid 4 mg/5 mL solution in vials
53150-0871-01	Zoledronic Acid 4 mg/5 mL solution in vials
23155-0170-31	Zoledronic Acid 4 mg/5 mL solution in vials
55111-0685-07	Zoledronic Acid 4 mg/5 mL solution in vials
60505-6110-00	Zoledronic Acid 4 mg/5 mL solution in vials
45963-0440-55	Zoledronic Acid 4 mg/5 mL solution in vials
47335-0962-41	Zoledronic Acid 4 mg/5 ml lyophilisate for solution for injection in vials
25021-0826-82	Zoledronic Acid 4 mg/100 mL solution in vials
00078-0387-25	Zometa 4 mg/5 mL solution in vials
00078-0590-61	Zometa 4 mg/100 mL solution in vials

HCPCS Code	Description
<u>J0129</u>	<u>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)</u>
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
<u>J1071</u>	<u>Injection, testosterone cypionate, 1 mg</u>
J1300	Injection, eculizumab, 10 mg
J1303	Injection, ravulizumab-cwvz, 10 mg
<u>J1602</u>	<u>Injection, golimumab, 1 mg, for intravenous use</u>
J1745	Injection, infliximab, excludes biosimilar, 10 mg
J2357	Injection, omalizumab, 5 mg
J2505	Injection, pegfilgrastim, 6 mg
<u>J3121</u>	<u>Injection, testosterone enanthate, 1 mg</u>
<u>J3145</u>	<u>Injection, testosterone undecanoate, 1 mg</u>
<u>J3245</u>	<u>Injection, tildrakizumab, 1 mg</u>
<u>J3262</u>	<u>Injection, tocilizumab, 1 mg</u>
J3357	Ustekinumab, for subcutaneous injection, 1mg
J3358	Ustekinumab, for intravenous injection, 1mg
J3380	Injection, vedolizumab, 1 mg
J3489	Injection, zoledronic acid, 1 mg
<u>J7170</u>	<u>Injection, emicizumab-kxwh, 0.5 mg</u>
J9035	Injection, bevacizumab, 10 mg
J9299	Injection, nivolumab, 1 mg
<u>J9311</u>	<u>Injection, rituximab 10 mg and hyaluronidase</u>
J9312	Injection, rituximab, 10 mg
J9355	Injection, trastuzumab, excludes biosimilar, 10 mg

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HCPCS Code	Description
Q5103	Injection, Infliximab-dyyb, biosimilar, (Inflixtra), 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
<u>S0189</u>	<u>Testosterone pellet, 75 mg</u>

National Drug Code	Description
<u>50242-0135-01</u>	<u>Actemra 20 mg/mL vial</u>
<u>50242-0136-01</u>	<u>Actemra 200 mg/10 mL vial</u>
<u>50242-0137-01</u>	<u>Actemra 400 mg/20 mL vial</u>
50242-0060-01	Avastin 100 mg/4 mL solution-in-vials vial
<u>50242-0060-10</u>	
50242-0061-01	Avastin 400 mg/16 mL solution-in-vials vial
<u>50242-0061-10</u>	
<u>67979-0511-43</u>	<u>Aveed 750 mg/3 mL vial</u>
<u>55513-0670-01</u>	<u>Avsola 100 mg vial</u>
50474-0700-62	Cimzia 2 x 200mg kit
50474-0710-79	Cimzia 2 x 200 mg/ml prefilled syringe (PFS) kit
50474-0710-81	Cimzia 6 x 200 mg/ml prefilled-syringe PFS kit
<u>00134-9570-01</u>	<u>Delatestryl (testosterone enanthate) 200 mg/mL vial</u>

National Drug Code	Description
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	<u>Depo-Testosterone (testosterone cypionate) 200 mg/mL vial</u>
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 powder for reconstitution <u>vial</u>
50242-0920-01	<u>Hemlibra 30 mg/mL</u>
50242-0922-01	<u>Hemlibra 105 mg/0.7 mL</u>
50242-0923-01	<u>Hemlibra 150 mg/mL</u>
50242-0921-01	<u>Hemlibra 60 mg/0.4 mL</u>
67457-0833-06	Fulphila 6 mg/0.6ml prefilled syringe <u>PFS</u>
50242-0333-01	Herceptin 420 mg powder for reconstitution
50242-0132-01	Herceptin 150 mg powder for reconstitution <u>vial</u>
50242-0132-10	
63459-0305-47	Herzuma 420 mg powder for reconstitution <u>vial</u>
63459-0303-43	Herzuma 150 mg powder for reconstitution <u>vial</u>

National Drug Code	Description
47335-0177-96 47335-0177-95	<u>Ilumya 100 mg/mL PFS</u>
32228-0001-0100069-0809-01	Inflectra 100 mg powder for reconstitution <u>vial</u>
55513-0132-01	Kanjinti 420 mg powder for reconstitution <u>vial</u>
<u>55513-0141-01</u>	<u>Kanjinti 150 mg vial</u>
55513-0190-01	Neulasta 6 mg/0.6 mL prefilled syringe PFS
54868-5229-0055513-0192-01	Neulasta 6 mg/0.6 mL prefilled syringe PFS with on-body injector
55513-0206-01	Mvasi 100 mg/4 mL solution in vials <u>vial</u>
55513-0207-01	Mvasi 400 mg/16 mL solution in vials <u>vial</u>
67457-0847-44 67457-0845-50	Ogivri 420 mg powder for reconstitution <u>vial</u>
67457-0991-15	Ogivri 150 mg powder for reconstitution <u>vial</u>
	Ontruzant 420 mg powder for reconstitution
00006-5033-02	Ontruzant 150 mg powder for reconstitution <u>vial</u>
00003-3774-12	Opdivo 100 mg/10 ml solution in vials <u>vial</u>
00003-3734-13	Opdivo 240 mg/24 ml solution in vials <u>vial</u>
00003-3772-11	Opdivo 40 mg/4 mL solution in vials <u>vial</u>
71336-1000-01	Onpattro 10 mg/5 mL solution in vials <u>vial</u>
<u>00003-2187-10</u> <u>00003-2187-13</u>	<u>Orencia 250 mg vial</u>
55513-0710-01	Prolia 60 mg/1 mL prefilled syringe PFS
00078-0435-61	Reclast 5 mg/100 mL solution in vials <u>vial</u>
35356-0351-01	Reclast 5 mg/100 mL solution in vials <u>vial</u>
57894-0030-01	Remicade 100 mg powder for reconstitution <u>vial</u>
<u>00006-4305-01</u> 00006-4305-02	Renflexis 100 mg powder for reconstitution <u>vial</u>
<u>50242-0051-10</u> 50242-0051-21	Rituxan 100 mg/10 mL solution in vials <u>vial</u>
50242-0053-06	Rituxan 500 mg/50 mL solution in vials <u>vial</u>
<u>50242-0108-01</u>	<u>Rituxan Hycela 1,400-23,400 mg/11.7 mL vial</u>
<u>50242-0109-01</u>	<u>Rituxan Hycela 1,600-26,800 mg/13.4 mL vial</u>
<u>00069-0238-01</u>	<u>Ruxience 100 mg/10 mL vial</u>
<u>00069-0249-01</u>	<u>Ruxience 500 mg/50 mL vial</u>
<u>57894-0350-01</u>	<u>Simponi Aria 50 mg/4 mL vial</u>
25682-0001-01	Soliris 300 mg/30 mL solution in vials <u>vial</u>
57894-0060-03	Stelara 45 mg/0.5 mL prefilled syringe PFS
57894-0060-02	Stelara 45 mg/0.5 mL solution in vials <u>vial</u>
57894-0061-03	Stelara 90 mg/1 mL prefilled syringe PFS
57894-0054-27	Stelara 130 mg/26 mL solution in vials <u>vial</u>

National Drug Code	Description
<u>66887-0004-01</u> <u>66887-0004-10</u> <u>66887-0004-20</u>	<u>Testopel 75 mg pellet</u>
<u>00069-0305-01</u> <u>00069-0306-01</u>	Trazimera 420 mg powder for reconstitution <u>vial</u>
	Trazimera 150 mg powder for reconstitution
<u>63459-0103-10</u>	Truxima 100 mg/10 mL solution in vial <u>vial</u>
<u>63459-0104-50</u>	Truxima 500 mg/50 mL solution in vial <u>vial</u>
<u>70114-0101-01</u>	Udenyca 6 mg/0.6 mL prefilled syringe <u>PFS</u>
<u>25682-0022-01</u>	Ultomiris 300 mg/30 mL solution in vial <u>vial</u>
<u>55513-0730-01</u>	Xgeva 120 mg/1.7 mL solution in vial <u>vial</u>
<u>50242-0040-6286</u>	Xolair 150 mg powder for reconstitution <u>vial</u>
<u>50242-0214-01</u>	Xolair 75 mg prefilled syringe <u>PFS</u>
<u>50242-0215-01</u> <u>50242-0215-86</u>	Xolair 150 mg prefilled syringe <u>PFS</u>
<u>61314-0866-01</u>	<u>Ziextenzo 6 mg/0.6 mL PFS</u>
<u>00069-0315-01</u>	Zirabev 100 mg/4 mL solution in vial <u>vial</u>
<u>00069-0342-01</u>	Zirabev 400 mg/16 mL solution in vial <u>vial</u>
<u>00409-4215-01</u> <u>00409-4215-05</u> <u>16714-0815-01</u> <u>16729-0242-31</u> <u>23155-0170-31</u> <u>25021-0801-66</u> <u>43598-0330-11</u> <u>51991-0065-98</u> <u>54288-0100-01</u> <u>55111-0685-07</u> <u>55150-0266-05</u> <u>63323-0961-98</u> <u>67457-0390-54</u> <u>68001-0366-22</u> <u>68001-0366-25</u>	<u>Zoledronic Acid 4 mg/5 mL vial</u>
<u>70860-0210-51</u>	<u>Zoledronic Acid 4 mg/100 mL vial</u>
<u>00409-4229-01</u> <u>23155-0186-31</u> <u>25021-0826-67</u> <u>25021-0826-82</u>	<u>Zoledronic Acid 4 mg/100 mL infusion</u>
<u>00078-0435-61</u> <u>25021-0830-82</u> <u>43598-0331-11</u> <u>51991-0064-98</u> <u>55111-0688-52</u> <u>63323-0966-00</u> <u>67457-0619-10</u>	<u>Zoledronic Acid 5 mg/100 mL vial</u>

National Drug Code	Description
<u>00409-4228-01</u> <u>25021-0830-82</u> <u>67457-0794-10</u> <u>70860-0802-82</u>	Zoledronic Acid 5 mg/100 mL infusion
25021-0830-82	Zoledronic Acid 5 mg/100 mL solution in vials
42023-0163-01	Zoledronic Acid 5 mg/100 mL solution in vials
43598-0331-11	Zoledronic Acid 5 mg/100 mL solution in vials
23155-0186-31	Zoledronic Acid 5 mg/100 mL solution in vials
55111-0688-52	Zoledronic Acid 5 mg/100 mL solution in vials
00143-9642-01	Zoledronic Acid 4 mg/5 mL solution in vials
47335-0035-40	Zoledronic Acid 4 mg/5 mL solution in vials
25021-0801-66	Zoledronic Acid 4 mg/5 mL solution in vials
42023-0151-01	Zoledronic Acid 4 mg/5 mL solution in vials
43598-0330-11	Zoledronic Acid 4 mg/5 mL solution in vials
53150-0871-01	Zoledronic Acid 4 mg/5 mL solution in vials
23155-0170-31	Zoledronic Acid 4 mg/5 mL solution in vials
55111-0685-07	Zoledronic Acid 4 mg/5 mL solution in vials
60505-6110-00	Zoledronic Acid 4 mg/5 mL solution in vials
45963-0440-55	Zoledronic Acid 4 mg/5 mL solution in vials
47335-0962-41	Zoledronic Acid 4 mg/5 mL lyophilisate for solution for injection in vials
25021-0826-82	Zoledronic Acid 4 mg/100 mL solution in vials
00078-0387-25	Zometa 4 mg/5 mL solution in vials
00078-0590-61	Zometa 4 mg/100 mL solution in vials

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 meters²) 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) Medicare does not have a National Coverage Determination (NCD) or Local Coverage Determinations (LCDs) that specifically addresses maximum dosages for the following medications:

- bevacizumab (Avastin[®])
- bevacizumab-awwb (Mvasi[™])
- bevacizumab-bvzr (Zirabev[™])
- certolizumab-pegol (Cimzia[®])
- denosumab (Prolia[®] & Xgeva[®])
- eculizumab (Soliris[®])
- infliximab (Remicade[®])
- infliximab-dyyb (Inflectra[™])
- infliximab-abda (Renflexis[™])
- nivolumab (Opdivo[®])
- omalizumab (Xolair[®])
- patisiran (Onpattro[™])
- pegfilgrastim (Neulasta[®])
- pegfilgrastim-cbqv (Udenyca[™])
- pegfilgrastim-jmdb (Fulphila[™])
- ravulizumab-cwvz (Ultomiris[™])
- rituximab (Rituxan[®])
- rituximab-abbs (Truxima[®])
-
- 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[®])

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 August 7, 2019)

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
TBD	<u>Added Actemra, Aveed, Delatestryl, Depo-Testosterone, Hemlibra, Ilumya, Ziextenzo, Orencia, Ruxience, Rituxan Hycela, Simponi Aria, Testopel to policy. Added frequency criteria to coverage rationale. Updated applicable codes and references.</u>

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 MCG™ Care Guidelines, 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.

DRAFT