UnitedHealthcare Community Plan

UnitedHealthcare® Community Plan
Medical Benefit Drug Policy

MAXIMUM DOSAGE

Policy Number: CSLA2020D0034W **Effective Date**:TBD

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Commercial Policy

- Maximum Dosage

APPLICATION

This Medical Benefit Drug Policy only applies to the 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

- Bevacizumab (Avastin®)
- **Bevacizumab-awwb (Mvasi™)**
- **Bevacizumab-bvzr (Zirabev™)**
- **Certolizumab pegol (Cimzia®)**
- Denosumab (Prolia® & Xgeva®)
- Eculizumab (Soliris®)
- Infliximab (Remicade®)
- Infliximab-abda (Renflexis™)

- Infliximab-dyyb (Inflectra™)
- Nivolumab (Opdivo®)
- Omalizumab (Xolair®)
- **Patisiran (Onpattro™)**
- Pegfilgrastim (Neulasta®)
- Pegfilgrastim-cbqv (Udenyca™)
- Pegfilgrastim-jmdb (Fulphila™)
- **Ravulizumab-cwvz (Ultomiris™)**
- **Rituximab-abbs (Truxima®)**
- Rituximab (Rituxan®)
- 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®)

~~Most medications have a maximum dosage based upon body surface area or patient weight or a set maximal dosage independent of patient body size, and are proven when used according to labeled indications or when otherwise supported by published clinical evidence.~~ The **use of** medications included in this policy when given **within the** ~~beyond~~ maximum dosage~~s~~ based upon body surface area or patient weight or a set maximal dosage independent of patient body size are proven when used according to labeled indications or when otherwise supported by published clinical evidence. ~~are not supported by package labeling or published clinical evidence and are unproven~~.

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

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

Medication Name		Diagnosis	Maximum Dosage per Administration	HCPCS Code	Maximum Allowed
Brand	Generic				
Avastin	bevacizumab		15 mg/kg	J9035	192 HCPCS units (10 mg per unit)
Mvasi	**bevacizumab-awwb**		**15 mg/kg**	**Q5107**	**192 HCPCS units (10 mg per unit)**
Zirabev	**bevacizumab-bvzr**		**15 mg/kg**	**Q5118**	**192 HCPCS units (10 mg per unit)**
Cimzia	**certolizumab pegol**		**400 mg total dose**	**J0717**	**400 HCPCS units (1 mg per unit)**
Entyvio	vedolizumab		300 mg	J3380	300 HCPCS units (1 mg per unit)
Herceptin	trastuzumab		8 mg/kg	J9355	103 HCPCS units (10 mg per unit)
Herzuma	**trastuzumab-pkrb**		**8 mg/kg**	**Q5113**	**103 HCPCS units (10 mg per unit)**
Kanjinti	**trastuzumab-anns**		**8 mg/kg**	**Q5117**	**103 HCPCS units (10 mg per unit)**

Medication Name		Diagnosis	Maximum Dosage per Administration	HCPCS Code	Maximum Allowed
Brand	Generic				
Ogivri	trastuzumab-dkst		8 mg/kg	Q5114	103 HCPCS units (10 mg per unit)
Ontruzant	trastuzumab-dttb		8 mg/kg	Q5112	103 HCPCS units (10 mg per unit)
Trazimera	trastuzumab-qyyp		8 mg/kg	Q5116	103 HCPCS units (10 mg per unit)
Neulasta	pegfilgrastim		6 mg total dose	J2505	1 HCPCS unit (6 mg per unit)
Fulphila	pegfilgrastim		6 mg total dose	Q5108	12 HCPCS unit (0.5mg per unit)
Udenyca	pegfilgrastim-cbqv		6 mg total dose	Q5111	12 HCPCS units (0.5mg per unit)
Opdivo	nivolumab		480 mg	J9299	480 HCPCS units (1 mg per unit)
Reclast	zoledronic acid		5 mg total dose	J3489	5 HCPCS units (1 mg per unit)
Zoledronic Acid					
Zometa			4 mg total dose		
Zoledronic Acid					
Remicade	infliximab		10 mg/kg	J1745	128 HCPCS units (10 mg per unit)
Inflectra	infliximab-dyyb		10 mg/kg	Q5103	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)
Renflexis	infliximab-abda		10 mg/kg	Q5104	128 HCPCS units (10 mg per unit)
Rituxan	rituximab		1,225 mg total dose	J9312	123 HCPCS units (10 mg per unit)
Truxima	rituximab-abbs		1,225 mg total dose	Q5115	123 HCPCS units (10 mg per unit)
Soliris	eculizumab	PNH	900 mg	J1300	90 HCPCS units (10 mg per unit)
		aHUS, MG	1200 mg		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)
Ultomiris	ravulizumab-cwvz		3,600 mg total dose	J1303	360 HCPCS units (10 mg per unit)
Xgeva	denosumab	Oncology	120 mg	J0897	120 HCPCS units (1 mg per unit)
Xolair	omalizumab	Asthma	375 mg	J2357	90 HCPCS units (5 mg per unit)

Medication Name		Diagnosis	Maximum Dosage per Administration	HCPCS Code	Maximum Allowed
Brand	Generic				
		Chronic Urticaria	300 mg		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.

Medication Name		Diagnosis	How Supplied	National Drug Code	Maximum Allowed
Brand	Generic				
Avastin	bevacizumab		100 mg/4 mL solution in vials	50242-0060-01	77 mL
			400 mg/16 mL solution in vials	50242-0061-01	
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
Cimzia	Certolizumab pegol		2 x 200mg kit	50474-0700-62	2 vials
			2 x 200mg/ml prefilled syringe kit	50474-0710-79	2 mL
			6 x 200 mg/ml prefilled syringe kit	50474-0710-81	2 mL
Entyvio	Vedolizumab		300 mg powder for reconstitution	64764-0300-20	1 vial
Fulphila	pegfilgrastim		6 mg/0.6ml prefilled syringe	67457-0833-06	0.6 mL
~~Herceptin~~	~~trastuzumab~~		~~440 mg powder for reconstitution~~	~~50242-0056-56~~	~~3 vials~~
			~~440 mg powder for reconstitution~~	~~50242-0134-68~~	~~3 vials~~
Herceptin	trastuzumab		420 mg powder for reconstitution	50242-0333-01	3 vials
			150 mg powder for reconstitution	50242-0132-01	3 vials
Herzuma	trastuzumab-pkrb		420 mg powder for reconstitution	63459-0305-47	3 vials
			150 mg powder for reconstitution	63459-0303-43	3 vials
Kanjinti	trastuzumab-anns		420 mg powder for reconstitution	55513-0132-01	3 vials
			150 mg powder for reconstitution		3 vials
Ogivri	trastuzumab-dkst		420 mg powder for reconstitution	67457-0847-44	3 vials
			150 mg powder for reconstitution	67457-0991-15	3 vials
Ontruzant	trastuzumab-dttb		420 mg powder for reconstitution		3 vials
			150 mg powder for	00006-5033-	3 vials

Medication Name		Diagnosis	How Supplied	National Drug Code	Maximum Allowed
Brand	Generic				
			reconstitution	02	
Trazimera	trastuzumab-qyyp		420 mg powder for reconstitution	00069-0305-01	3 vials
			150 mg powder for reconstitution		3 vials
Neulasta	pegfilgrastim		6 mg/0.6 mL prefilled syringe	54868-5229-00	0.6 mL
				55513-0190-01	
			6 mg/0.6 mL prefilled syringe with on-body Injector	55513-0190-01	
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
Prolia	denosumab	Osteoporosis	60 mg/1 mL prefilled syringe	55513-0710-01	1 mL
Reclast	zoledronic acid		5 mg/100 mL solution in vials	00078-0435-61	100 mL
				35356-0351-01	
Remicade	infliximab		100 mg powder for reconstitution	57894-0030-01	13 vials
Renflexis	infliximab-abda		100 mg powder for reconstitution	00006-4305-02	13 vials
Inflectra	infliximab-dyyb		100 mg powder for reconstitution	32228-0001-01	13 vials
Rituxan	rituximab		100 mg/10 mL solution in vials	50242-0051-21	130 mL
			500 mg/50 mL solution in vials	50242-0053-06	
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
Soliris	eculizumab	PNH	300 mg/30 mL solution in vials	25682-0001-01	90 mL
		aHUS, MG			120 mL
Stelara	ustekinumab		45 mg/0.5 mL prefilled syringe	57894-0060-03	0.5 mL
			45 mg/0.5 mL solution in vials	57894-0060-02	
			90 mg/1 mL prefilled syringe	57894-0061-03	1 mL
		Crohn's Disease	130 mg/26 mL solution in vials	57894-0054-27	104 mL
Ultomiris	Ravulizumab-cwvz		300 mg/30 mL solution in vials	25682-0022-01	360 mL
Udenyca	pegfilgrastim-cbqv		6 mg/0.6ml prefilled syringe	70114-0101-01	0.6 mL
Xgeva	denosumab	Oncology	120 mg/1.7 mL solution in vials	55513-0730-01	1.7 mL
Xolair	omalizumab	Asthma	150 mg powder for reconstitution	50242-0040-62	~~3~~ 2 vials
			150 mg prefilled syringe	50242-0215-01	2 mL
			75 mg prefilled syringe	50242-0214-01	1 mL
		Chronic	150 mg powder for reconstitution	50242-0040-62	2 vials

Medication Name		Diagnosis	How Supplied	National Drug Code	Maximum Allowed
Brand	Generic				
		Urticaria	150 mg prefilled syringe	50242-0215-01	2 mL
			75 mg prefilled syringe	50242-0214-01	1 mL
Zoledronic Acid	zoledronic acid		5 mg/100 mL solution in vials	25021-0830-82	100 mL
				42023-0163-01	
				43598-0331-11	
				23155-0186-31	
				55111-0688-52	
			4 mg/5 mL solution in vials	00143-9642-01	5 mL
				47335-0035-40	
				25021-0801-66	
				42023-0151-01	
				43598-0330-11	
				53150-0871-01	
				23155-0170-31	
				55111-0685-07	
				60505-6110-00	
				45963-0440-55	
			4 mg/5 ml lyophilisate for solution for injection in vials	47335-0962-41	5 mL
			4 mg/100 mL solution in vials	25021-0826-82	100 mL
Zometa	zoledronic acid		4 mg/5 mL solution in vials	00078-0387-25	5 mL
			4 mg/100 mL solution in vials	00078-0590-61	100 mL

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)
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

HCPCS Code	Description
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, (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

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
64764-0300-20	Entyvio 300 mg powder for reconstitution
67457-0833-06	Fulphila 6 mg/0.6ml prefilled syringe
~~50242-0056-56~~	~~Herceptin 440 mg powder for reconstitution~~
~~50242-0134-68~~	~~Herceptin 440 mg powder for reconstitution~~
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
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

National Drug Code	Description
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
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

National Drug Code	Description
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 meters^2) in the U.S. (adult male, 30 to 39 years, Fryar, 2016).

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

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

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) 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)~~Medicare does not have a National Coverage Determination (NCD) that addresses the maximum dosage for each of the following medications listed below. Local Coverage Determinations (LCDs) or Local Coverage Articles (LCAs) may exist for some of medications listed below. These LCDs/LCAs are available at http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx:~~

- ~~Bevacizumab (Avastin®)~~
  - ~~Bevacizumab - Related to LCD L33394~~
  - ~~Billing and Coding Information Regarding Uses, Including Off-Label Uses, of Anti-Vascular Endothelial Growth Factor (anti-VEGF), for The Treatment of Ophthalmological Diseases~~
- ~~Denosumab (Prolia® & Xgeva®) J0897~~
  - ~~Bisphosphonates (Intravenous [IV]) and Monoclonal Antibodies in the Treatment of Osteoporosis and Their Other Indications~~
- ~~Eculizumab (Soliris®)~~
  - ~~Drugs and Biologics (Non-chemotherapy)~~
  - ~~Eculizumab (Soliris®) - Related to LCD L33394~~
- ~~Infliximab (Remicade®)~~
  - ~~Drugs and Biologics (Non-chemotherapy)~~
  - ~~Infliximab~~
  - ~~Infliximab (Remicade™)~~
- ~~Infliximab-dyyb (Inflectra™)~~
  - ~~Drugs and Biologics (Non-chemotherapy)~~
  - ~~Infliximab~~
  - ~~Infliximab (Remicade™)~~
- ~~Infliximab-abda (Renflexis™)~~
  - ~~Drugs and Biologics (Non-chemotherapy)~~
  - ~~Infliximab~~
  - ~~Infliximab (Remicade™)~~
- ~~Nivolumab (Opdivo®)~~
  - ~~Nivolumab - Related to LCD L33394~~
  - ~~Billing and Coding for Chemotherapy~~
- ~~Omalizumab (Xolair®)~~
  - ~~Omalizumab (Xolair®)~~
  - ~~Drugs and Biologics (Non-chemotherapy)~~
- ~~Pegfilgrastim (Neulasta®)~~
  - ~~Human Granulocyte/Macrophage Colony Stimulating Factors~~
  - ~~Pegfilgrastim (Neulasta®)~~
  - ~~White Cell Colony Stimulating Factors~~
- ~~Pegfilgrastim-cbqv (Udenyca™)~~
  - ~~Human Granulocyte/Macrophage Colony Stimulating Factors~~
  - ~~Pegfilgrastim (Neulasta®)~~
  - ~~White Cell Colony Stimulating Factors~~
- ~~Pegfilgrastim-jmdb (Fulphila™)~~
  - ~~Human Granulocyte/Macrophage Colony Stimulating Factors~~
  - ~~Pegfilgrastim (Neulasta®)~~
  - ~~White Cell Colony Stimulating Factors~~
- ~~Rituximab (Rituxan®)~~
  - ~~Rituximab (Rituxan®)~~
- ~~Trastuzumab (Herceptin®)~~
  - ~~Trastuzumab (Herceptin®)~~
- ~~Ustekinumab (Stelara®)~~
  - ~~Self-Administered Drug Exclusion List (SAD List)~~
  - ~~Billing and Coding of Drug and Biological Infusions~~
- ~~Vedolizumab (Entyvio®)~~
  - ~~LCDs/LCAs do not exist at this time~~
- ~~Zoledronic Acid (zoledronic acid, Reclast® and Zometa®)~~

~~o LCDs/LCAs do not exist at this time~~
~~(Accessed March 20, 2019)~~

REFERENCES

1. Avastin [package insert]. South San Francisco, CA: Genentech, Inc.; June 2018.
2. 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.
3. 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.
4. Herceptin [prescribing information]. South San Francisco, CA: Genentech, Inc.; October 2018.
5. Neulasta [prescribing information]. Thousand Oaks, CA: Amgen Inc.; June 2018.
6. Reclast [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2017.
7. Remicade [prescribing information]. Horsham, PA: Janssen Biotech Inc.; June 2018.
8. Rituxan [prescribing information]. South San Francisco, CA: Genentech, Inc.; October 2018.
9. Zometa [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2016.
10. Reimbursement Codes [database online]. Rocky Hill, CT: RJ Health Systems International, LLC.; 2018.
11. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018.
12. Inflectra [prescribing information]. New York, NY: Pfizer Labs; July 2018.
13. Stelara [prescribing information]. Horsham, PA: Janssen Biotech, Inc. June 2018.
14. Entyvio [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; February 2018.
15. Soliris [prescribing information]. Boston, MA: Alexion Pharmaceuticals, Inc.; July 2018.
16. Renflexis [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; November 2017.
17. Xolair [prescribing information]. South San Francisco, CA: Genentech, Inc., September 2018.
18. Fulphila [prescribing information]. Rockford, IL: Mylan Institutional, LLC, June 2018.
19. Opdivo [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company, February 2019.
20. Udenyca [prescribing information]. Redwood City, CA: Coherus BioSciences, Inc, November 2018.
21. Prolia [prescribing information]. Thousand Oaks, CA: Amgen Inc.; June 2018.
22. Xgeva [prescribing information]. Thousand Oaks, CA: Amgen Inc.; June 2018.
23. Cimzia [prescribing information]. Smyrna, GA: UCB, Inc.; March 2019
24. Herzuma [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; May 2019
25. Kanjinti [prescribing information]. Thousand Oaks, CA: Amgen Inc.; June 2019
26. Mvasi [prescribing information]. Thousand Oaks CA: Amgen Inc.; June 2019
27. Ogivri [prescribing information]. Steinhausen, Switzerland: Mylan GmbH; April 2019
28. Onpattro [prescribing information]. Cambridge, MA: Alnylam Pharmaceuticals, Inc.; August 2018
29. Ontruzant [prescribing information]. Whitehouse Station, NJ: Merck & Co., Inc.; January 2019
30. Trazimera [prescribing information]. New York, NY: Pfizer Inc.; March 2019
31. Truxima [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; May 2019
32. Ultomiris [prescribing information]. Boston, MA: Alexion Pharmaceuticals, Inc.; December 2018
33. Zirabev [prescribing information]. New York, NY: Pfizer Inc.; June 2019

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
TBD	Added Cimzia, Herzuma, Kanjinti, Mvasi, Ogivri, Onpattro, Ontruzant, Trazimera, Truxima, Ultomiris, and Zirabev to the policy.

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.