

# Maximum Dosage and Frequency

**Policy Number:** 2024D0034AM  
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[➔ Instructions for Use](#)

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## Related Commercial Policies

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| <ul style="list-style-type: none"> <li>• <a href="#">Actemra® (Tocilizumab) Injection for Intravenous Infusion</a></li> <li>• <a href="#">Cimzia® (Certolizumab Pegol)</a></li> <li>• <a href="#">Complement Inhibitors (Soliris® &amp; Ultomiris®)</a></li> <li>• <a href="#">Denosumab (Prolia® &amp; Xgeva®)</a></li> <li>• <a href="#">Entyvio® (Vedolizumab)</a></li> <li>• <a href="#">Ilaris® (Canakinumab)</a></li> <li>• <a href="#">Ilumya® (Tildrakizumab-Asmn)</a></li> <li>• <a href="#">Infliximab (Avsola®, Inflectra®, Remicade®, &amp; Renflexis®)</a></li> <li>• <a href="#">Krystexxa® (Pegloticase)</a></li> <li>• <a href="#">Leqvio® (Inclisiran)</a></li> <li>• <a href="#">Neonatal Fc Receptor Blockers (Vyvgart®, Vyvgart® Hytrulo, &amp; Rystiggo®)</a></li> <li>• <a href="#">Ocrevus® (Ocrelizumab)</a></li> <li>• <a href="#">Oncology Medication Clinical Coverage</a></li> <li>• <a href="#">Ophthalmologic Complement Inhibitors</a></li> <li>• <a href="#">Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors</a></li> </ul> | <ul style="list-style-type: none"> <li>• <a href="#">Orencia® (Abatacept) Injection for Intravenous Infusion</a></li> <li>• <a href="#">Qalsody® (Tofersen)</a></li> <li>• <a href="#">Radicava® (Edaravone)</a></li> <li>• <a href="#">Respiratory Interleukins (Cinqair®, Fasenna®, &amp; Nucala®)</a></li> <li>• <a href="#">Rituximab (Riabni™, Rituxan®, Ruxience®, &amp; Truxima®)</a></li> <li>• <a href="#">RNA-Targeted Therapies (Amvuttra® and Onpattro®)</a></li> <li>• <a href="#">Simponi Aria® (Golimumab) Injection for Intravenous Infusion</a></li> <li>• <a href="#">Skyrizi® (Risankizumab-Rzaa)</a></li> <li>• <a href="#">Spevigo® (Spesolimab-Sbzo)</a></li> <li>• <a href="#">Stelara® (Ustekinumab)</a></li> <li>• <a href="#">Testosterone Replacement or Supplementation Therapy</a></li> <li>• <a href="#">Tezspire® (Tezepelumab-Ekko)</a></li> <li>• <a href="#">Vyepti® (Eptinezumab-Jjmr)</a></li> <li>• <a href="#">White Blood Cell Colony Stimulating Factors</a></li> <li>• <a href="#">Xolair® (Omalizumab)</a></li> </ul> |
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## Community Plan Policy

- [Maximum Dosage and Frequency](#)

## Coverage Rationale

[➔ See Benefit Considerations](#)

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

## Drug Products

- abatacept (Orencia<sup>®</sup>)
- aflibercept (Eylea<sup>®</sup>)
- atezolizumab (Tecentriq<sup>®</sup>)
- avelumab (Bavencio<sup>®</sup>)
- benralizumab (Fasenra<sup>®</sup>)
- bevacizumab (Avastin<sup>®</sup>)
- bevacizumab-adcd (Vegzelma<sup>®</sup>)
- bevacizumab-awwb (Mvasi<sup>™</sup>)
- bevacizumab-bvzr (Zirabev<sup>®</sup>)
- bevacizumab-maly (Almysys<sup>®</sup>)
- brolocizumab-dblI (Beovu<sup>®</sup>)
- canakinumab (Ilaris<sup>®</sup>)
- cemiplimab-rwlc (Libtayo<sup>®</sup>)
- certolizumab pegol (Cimzia<sup>®</sup>)
- denosumab (Prolia<sup>®</sup> & Xgeva<sup>®</sup>)
- durvalumab (Imfinzi<sup>®</sup>)
- eculizumab (Soliris<sup>®</sup>)
- edaravone (Radicava<sup>®</sup>)
- efgartigimod alfa-fcab (Vyvgart<sup>®</sup>)
- efgartigimod alfa and hyaluronidase-qvfc (Vyvgart<sup>®</sup> Hytrulo)
- eflapegrastim-xnst (Rolvedon<sup>™</sup>)
- emicizumab-kxwh (Hemlibra<sup>®</sup>)
- eptinezumab-jjmr (Vyepi<sup>®</sup>)
- faricimab-svoa (Vabysmo<sup>™</sup>)
- golimumab (Simponi Aria<sup>®</sup>)
- inclisiran (Leqvio<sup>®</sup>)
- infliximab (Remicade<sup>®</sup>)
- infliximab-axxq (Avsola<sup>™</sup>)
- infliximab-dyyb (Inflectra<sup>®</sup>)
- infliximab-abda (Renflexis<sup>®</sup>)
- ipilimumab (Yervoy<sup>®</sup>)
- mepolizumab (Nucala<sup>®</sup>)
- nivolumab (Opdivo<sup>®</sup>)
- ocrelizumab (Ocrevus<sup>®</sup>)
- omalizumab (Xolair<sup>®</sup>)
- patisiran (Onpattro<sup>®</sup>)
- pegcetacoplan (Syfovre<sup>™</sup>)
- pegfilgrastim (Neulasta<sup>®</sup>)
- pegfilgrastim-apgf (Nyvepria<sup>™</sup>)
- pegfilgrastim-cbqv (Udenyca<sup>®</sup>)
- pegfilgrastim-fpgk (Stimufend<sup>®</sup>)
- pegfilgrastim-jmdb (Fulphila<sup>™</sup>)
- pegfilgrastim-pbbk (Fynetra<sup>®</sup>)
- pegfilgrastim-bmez (Ziextenzo<sup>®</sup>)
- pegloticase (Krystexxa<sup>®</sup>)
- pembrolizumab (Keytruda<sup>®</sup>)
- ranibizumab (Lucentis<sup>®</sup>)
- ranibizumab-nuna (Byooviz<sup>™</sup>)
- ranibizumab-eqrn (Cimerli<sup>™</sup>)
- ravulizumab-cwvz (Ultomiris<sup>®</sup>)
- reslizumab (Cinqair<sup>®</sup>)
- risankizumab-rzaa (Skyrizi<sup>®</sup>)
- rituximab (Rituxan<sup>®</sup>)
- rituximab-pvvr (Ruxience<sup>™</sup>)
- rituximab-abbs (Truxima<sup>®</sup>)
- rituximab-arrx (Riabni<sup>™</sup>)
- rituximab and hyaluronidase (Rituxan Hycela<sup>®</sup>)
- rozanolixizumab-noli (Rystiggo<sup>®</sup>)
- spesolimab-sbzo (Spevigo<sup>®</sup>)
- testosterone cypionate (Depo-Testosterone<sup>®</sup>)
- testosterone enanthate
- testosterone pellets (Testopel<sup>®</sup>)
- testosterone undecanoate (Aveed<sup>®</sup>)
- tezepelumab-ekko (Tezspire<sup>®</sup>)
- tildrakizumab-asmn (Ilumya<sup>™</sup>)
- tocilizumab (Actemra<sup>®</sup>)
- tofersen (Qalsody<sup>™</sup>)
- trastuzumab (Herceptin<sup>®</sup>)
- trastuzumab-anns (Kanjinti<sup>™</sup>)
- trastuzumab-dkst (Ogivri<sup>™</sup>)
- trastuzumab-dttb (Ontruzant<sup>®</sup>)
- trastuzumab-pkrb (Herzuma<sup>®</sup>)
- trastuzumab-qyyp (Trazimera<sup>™</sup>)
- ustekinumab (Stelara<sup>®</sup>)
- vedolizumab (Entyvio<sup>®</sup>)
- vutrisiran (Amvuttra<sup>™</sup>)
- zoledronic acid (zoledronic acid, Reclast<sup>®</sup>)

**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<br>(1 mg per unit)     |
| Avastin           | bevacizumab              | 15 mg/kg                          | J9035      | 240 HCPCS units<br>(10 mg per unit)    |
| Vegzelma          | bevacizumab-adcd         | 15 mg/kg                          | Q5129      | 240 HCPCS units<br>(10 mg per unit)    |
| Mvasi             | bevacizumab-awwb         | 15 mg/kg                          | Q5107      | 240 HCPCS units<br>(10 mg per unit)    |
| Zirabev           | bevacizumab-bvzr         | 15 mg/kg                          | Q5118      | 240 HCPCS units<br>(10 mg per unit)    |
| Alymsys           | bevacizumab-maly         | 15 mg/kg                          | Q5126      | 240 HCPCS units<br>(10 mg per unit)    |
| Aveed             | testosterone undecanoate | 750 mg                            | J3145      | 750 HCPCS units<br>(1 mg per unit)     |
| Cimzia            | certolizumab pegol       | 400 mg                            | J0717      | 400 HCPCS units<br>(1 mg per unit)     |
| Cinqair           | reslizumab               | 3 mg/kg                           | J2786      | 500 HCPCS units<br>(1 mg per unit)     |
| N/A               | testosterone enanthate   | 400 mg                            | J3121      | 400 HCPCS units<br>(1 mg per unit)     |
| Depo-Testosterone | testosterone cypionate   | 400 mg                            | J1071      | 400 HCPCS units<br>(1 mg per unit)     |
| Entyvio           | vedolizumab              | 300 mg                            | J3380      | 300 HCPCS units<br>(1 mg per unit)     |
| Fasenra           | benralizumab             | 30 mg                             | J0517      | 30 HCPCS units<br>(1 mg per unit)      |
| Hemlibra          | emicizumab-kxwh          | 6mg/kg                            | J7170      | 1,680 HCPCS units<br>(0.5 mg per unit) |
| Herceptin         | trastuzumab              | 8 mg/kg                           | J9355      | 126 HCPCS units<br>(10 mg per unit)    |
| Herzuma           | trastuzumab-pkrb         | 8 mg/kg                           | Q5113      | 126 HCPCS units<br>(10 mg per unit)    |
| Kanjinti          | trastuzumab-anns         | 8 mg/kg                           | Q5117      | 126 HCPCS units<br>(10 mg per unit)    |
| Ogivri            | trastuzumab-dkst         | 8 mg/kg                           | Q5114      | 126 HCPCS units<br>(10 mg per unit)    |
| Ontruzant         | trastuzumab-dttb         | 8 mg/kg                           | Q5112      | 126 HCPCS units<br>(10 mg per unit)    |
| Trazimera         | trastuzumab-qyyp         | 8 mg/kg                           | Q5116      | 126 HCPCS units<br>(10 mg per unit)    |
| Ilaris            | canakinumab              | 300 mg                            | J0638      | 300 HCPCS units<br>(1 mg per unit)     |
| Ilumya            | tildrakizumab-asmn       | 100 mg                            | J3245      | 100 HCPCS units<br>(1 mg per unit)     |

| Medication Name |                        | Maximum Dosage Per Administration | HCPCS Code | Maximum Allowed                      |
|-----------------|------------------------|-----------------------------------|------------|--------------------------------------|
| Brand           | Generic                |                                   |            |                                      |
| Leqvio          | inclisiran             | 284 mg                            | J1306      | 284 HCPCS units<br>(1 mg per unit)   |
| Neulasta        | pegfilgrastim          | 6 mg                              | J2506      | 12 HCPCS unit<br>(0.5 mg per unit)   |
| Nyvepria        | pegfilgrastim-<br>apgf | 6 mg                              | Q5122      | 12 HCPCS units<br>(0.5mg per unit)   |
| Fulphila        | pegfilgrastim-<br>jmdb | 6 mg                              | Q5108      | 12 HCPCS units<br>(0.5mg per unit)   |
| Fylnetra        | pegfilgrastim-<br>pbbk | 6 mg                              | Q5130      | 12 HCPCS units<br>(0.5mg per unit)   |
| Stimufend       | pegfilgrastim-<br>fpgk | 6 mg                              | Q5127      | 12 HCPCS units<br>(0.5mg per unit)   |
| Udenyca         | pegfilgrastim-<br>cbqv | 6 mg                              | Q5111      | 12 HCPCS units<br>(0.5mg per unit)   |
| Ziextenzo       | pegfilgrastim-<br>bmez | 6 mg                              | Q5120      | 12 HCPCS units<br>(0.5mg per unit)   |
| Rolvedon        | eflapegrastim-<br>xnst | 13.2 mg                           | J1449      | 132 HCPCS units<br>(0.1mg per unit)  |
| Krystexxa       | pegloticase            | 8 mg                              | J2507      | 8 HCPCS units<br>(1mg per unit)      |
| Nucala          | mepolizumab            | 300 mg                            | J2182      | 300 HCPCS units<br>(1 mg per unit)   |
| Ocrevus         | ocrelizumab            | 600 mg                            | J2350      | 600 HCPCS units<br>(1 mg per unit)   |
| Opdivo          | nivolumab              | 480 mg                            | J9299      | 480 HCPCS units<br>(1 mg per unit)   |
| Orencia         | abatacept              | 1000 mg                           | J0129      | 100 HCPCS units<br>(10 mg per unit)  |
| Reclast         | zoledronic acid        | 5 mg                              | J3489      | 5 HCPCS units<br>(1 mg per unit)     |
| Zoledronic Acid | zoledronic acid        | 5 mg                              | J3489      | 5 HCPCS units<br>(1 mg per unit)     |
| Avsola          | infliximab-axxq        | 10 mg/kg                          | Q5121      | 150 HCPCS units<br>(10 mg per unit)  |
| Inflectra       | infliximab-dyyb        | 10 mg/kg                          | Q5103      | 150 HCPCS units<br>(10 mg per unit)  |
| Remicade        | infliximab             | 10 mg/kg                          | J1745      | 150 HCPCS units<br>(10 mg per unit)  |
| Renflexis       | infliximab-abda        | 10 mg/kg                          | Q5104      | 150 HCPCS units<br>(10 mg per unit)  |
| Onpattro        | patisiran              | 30 mg                             | J0222      | 300 HCPCS units<br>(0.1 mg per unit) |
| Amvuttra        | vutrisiran             | 25 mg                             | J0225      | 25 HCPCS units<br>(1 mg per unit)    |

| Medication Name |  | Maximum Dosage Per Administration   | HCPCS Code | Maximum Allowed                     |
|-----------------|--|---|------------|-------------------------------------|
| Brand           | Generic                                  |   |            |                                     |
| Prolia          | denosumab                                | 60 mg   | J0897      | 60 HCPCS units<br>(1 mg per unit)   |
| Xgeva           | denosumab                                | 120 mg  | J0897      | 120 HCPCS units<br>(1 mg per unit)  |
| Qalsody         | tofersen                                 | 100 mg  | J1304      | 100 HCPCS units<br>(1 mg per unit)  |
| Radicava        | edaravone                                | 60 mg   | J1301      | 60 HCPCS units<br>(1 mg per unit)   |
| Rituxan         | rituximab                                | 500mg/m <sup>2</sup>  | J9312      | 150 HCPCS units<br>(10 mg per unit) |
| Ruxience        | rituximab-pvvr                           | 500mg/m <sup>2</sup>  | Q5119      | 150 HCPCS units<br>(10 mg per unit) |
| Truxima         | rituximab-abbs                           | 500mg/m <sup>2</sup>  | Q5115      | 150 HCPCS units<br>(10 mg per unit) |
| Riabni          | rituximab-arrx                           | 500mg/m <sup>2</sup>  | Q5123      | 150 HCPCS units<br>(10 mg per unit) |
| Rituxan Hycela  | rituximab and hyaluronidase              | 1,600 mg  | J9311      | 160 HCPCS units<br>(10 mg per unit) |
| Rystiggo        | rozanolixizumab-noli                     | 840 mg  | J9333      | 840 HCPCS units<br>(1 mg per unit)  |
| Simponi Aria    | golimumab                                | 2 mg/kg   | J1602      | 300 HCPCS units<br>(1 mg per unit)  |
| Soliris         | eculizumab                               | 1200 mg   | J1300      | 120 HCPCS units<br>(10 mg per unit) |
| Spevigo         | spesolimab-sbzo                          | 900 mg  | J1747      | 900 HCPCS units<br>(1 mg per unit)  |
| Stelara         | ustekinumab                              | 90 mg   | J3357      | 90 HCPCS units<br>(1 mg per unit)   |
|                 |  | 520 mg  | J3358      | 520 HCPCS units<br>(1 mg per unit)  |
| Testopel        | testosterone pellet                      | 450 mg  | S0189      | 6 HCPCS units<br>(75 mg per unit)   |
| Tezspire        | tezepelumab-ekko                         | 210 mg  | J2356      | 210 HCPCS units<br>(1mg per unit)   |
| Ultomiris       | ravulizumab-cwvz                         | 3,600 mg  | J1303      | 360 HCPCS units<br>(10 mg per unit) |
| Vyepti          | eptinezumab-jjmr                         | 300 mg  | J3032      | 300 HCPCS units<br>(1 mg per unit)  |
| Vyvgart         | efgartigimod alfa-fcab                   | 1200 mg   | J9332      | 600 HCPCS units<br>(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<br>(2mg per unit)   |
| Xolair          | omalizumab                               | 600 mg  | J2357      | 120 HCPCS units<br>(5 mg per unit)  |

| Medication Name |                   | Maximum Dosage Per Administration | HCPCS Code | Maximum Allowed                     |
|-----------------|-------------------|-----------------------------------|------------|-------------------------------------|
| Brand           | Generic           |                                   |            |                                     |
| Bavencio        | avelumab          | 800 mg                            | J9023      | 80 HCPCS units<br>(10 mg per unit)  |
| Imfinzi         | durvalumab        | 1,500 mg                          | J9173      | 150 HCPCS units<br>(10 mg per unit) |
| Keytruda        | pembrolizumab     | 400 mg                            | J9271      | 400 HCPCS units<br>(1 mg per unit)  |
| Libtayo         | cemiplimab-rwlc   | 350 mg                            | J9119      | 350 HCPCS units<br>(1 mg per unit)  |
| Tecentriq       | atezolizumab      | 1,680 mg                          | J9022      | 168 HCPCS units<br>(10 mg per unit) |
| Yervoy          | ipilimumab        | 10 mg/kg                          | J9228      | 1400 HCPCS units<br>(1 mg per unit) |
| Skyrizi         | risankizumab-rzaa | 600 mg                            | J2327      | 600 HCPCS units<br>(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<br>50242-0136-01<br>50242-0137-01 | 40 mL           |
| Avastin         | bevacizumab              | 100 mg/4mL vials   | 50242-0060-01<br>50242-0060-10                  | 12 mL           |
|                 |                          | 400 mg/16 mL vials | 50242-0061-01<br>50242-0061-10                  | 96 mL           |
| Vegzelma        | bevacizumab-adcd         | 100 mg/4 mL vials  | 32228-0011-01<br>32228-0011-02                  | 12 mL           |
|                 |                          | 400 mg/16 mL vials | 32228-0011-03<br>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<br>70121-1754-07                  | 12 mL           |
|                 |                          | 400mg/16mL vials   | 70121-1755-01<br>70121-1755-07                  | 96 mL           |
| Aveed           | testosterone undecanoate | 750 mg/3 mL        | 67979-0511-43                                   | 3 mL            |

| Medication Name   |                        | How Supplied                              | National Drug Code   | Maximum Allowed |
|-------------------|------------------------|---|--|-----------------|
| Brand             | Generic                |   |  |                 |
| 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<br>00574-0821-05<br>00591-3221-26  | 2 mL            |
| Depo-Testosterone | testosterone cypionate | 200 mg/mL                                 | 00009-0085-10<br>00009-0086-01<br>00009-0086-10<br>00009-0347-02<br>00009-0417-01<br>00009-0417-02<br>00009-0520-01<br>00009-0520-10<br>00143-9659-01<br>00143-9726-01<br>00409-6557-01<br>00409-6562-01<br>00409-6562-02<br>00409-6562-20<br>00409-6562-22<br>00517-1830-01<br>00574-0820-01<br>00574-0820-10<br>00574-0827-01<br>00574-0827-10<br>00591-4128-79<br>50090-0330-00<br>52536-0625-01<br>52536-0625-10<br>62756-0015-40<br>62756-0016-40<br>62756-0017-40<br>63874-1061-01<br>64980-0467-99<br>69097-0536-37<br>69097-0537-31<br>69097-0537-37<br>69097-0802-32<br>69097-0802-37<br>76420-0650-01<br>76519-1210-00 | 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            |

| Medication Name |                    | How Supplied                          | National Drug Code             | Maximum Allowed |
|-----------------|--------------------|---------------------------------------|--------------------------------|-----------------|
| Brand           | Generic            |                                       |                                |                 |
| 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<br>50242-0132-10 | 8 vials         |
| Herzuma         | trastuzumab-pkrb   | 420 mg vial                           | 63459-0305-47<br>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<br>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<br>00006-5034-02 | 3 vials         |
| Trazimera       | trastuzumab-qyyp   | 420 mg vial                           | 00069-0305-01<br>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       | pegloticase        | 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<br>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<br>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<br>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        | rozanolixizumab-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           |
| Stelara         | ustekinumab                 | 45 mg/0.5 mL PFS         | 57894-0060-03                                   | 0.5 mL          |
|                 |                             | 45 mg/0.5 mL vials       | 57894-0060-02                                   | 0.5 mL          |
|                 |                             | 90 mg/1 mL PFS           | 57894-0061-03                                   | 1 mL            |
|                 |                             | 130 mg/26 mL vials       | 57894-0054-27                                   | 104 mL          |
| Testopel        | testosterone pellet         | 75 mg pellet             | 66887-0004-01<br>66887-0004-10<br>66887-0004-20 | 6 pellets       |

| Medication Name |  | How Supplied                                  | National Drug Code  | Maximum Allowed |
|-----------------|--|---|---|-----------------|
| Brand           | Generic                                  |   |   |                 |
| 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         |
| 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           |
| Vyvgart 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         |
|                 |  | 150 mg/1 mL PFS                               | 50242-0215-01   | 4 mL            |
|                 |  | 75 mg/ 0.5 mL PFS                             | 50242-0214-01   | 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<br>70510-2171-02  | 200 mL          |
| Reclast         | zoledronic acid                          | 4 mg/5 mL vials                               | 00409-4215-01<br>00409-4215-05<br>16714-0815-01<br>16729-0242-31<br>23155-0170-31<br>25021-0801-66<br>43598-0330-11<br>51991-0065-98<br>54288-0100-01<br>55111-0685-07<br>55150-0266-05<br>63323-0961-98<br>67457-0390-54<br>68001-0366-22<br>68001-0366-25 | 5 mL            |
|                 |  | 4 mg/100 mL vials                             | 70860-0210-51   | 100 mL          |
|                 |  | 4 mg/100 mL infusion                          | 00409-4229-01<br>23155-0186-31<br>25021-0826-67<br>25021-0826-82  | 100 mL          |
|                 |  | 5mg/100 mL vials                              | 00078-0435-61<br>25021-0830-82<br>43598-0331-11<br>51991-0064-98<br>55111-0688-52<br>63323-0966-00<br>67457-0619-10   | 100 mL          |

| Medication Name |                 | How Supplied         | National Drug Code   | Maximum Allowed |
|-----------------|-----------------|----------------------|--|-----------------|
| Brand           | Generic         |                      |  |                 |
| Reclast         | zoledronic acid | 5 mg/100 mL infusion | 00409-4228-01<br>25021-0830-82<br>67457-0794-10<br>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           |
| Keytruda        | pembrolizumab   | 50 mg vials          | 00006-3029-01<br>00006-3029-02                                   | 8 vials         |
|                 |                 | 100 mg/4 mL vials    | 00006-3026-01<br>00006-3026-02<br>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 Oxford Health Plans without FDA approved dosing, the frequencies are derived from available clinical evidence. This list may not be inclusive of all medications listed and is subject to change.

| Medication Name |                  | Diagnosis  | Maximum Frequency   |
|-----------------|------------------|--|---|
| Brand           | Generic          |  |   |
| Actemra         | tocilizumab      | 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 1.25 mg (0.05 mL) near-monthly into affected eyes during the first 12 months, with fewer injections needed in subsequent years. Maximum of 12 doses per year per eye. |
|                 |                  | Diabetic macular edema   |   |

| Medication Name |                          | Diagnosis  | Maximum Frequency   |
|-----------------|--------------------------|--|---|
| Brand           | Generic                  |  |   |
| Avastin         | bevacizumab              | Macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO) | The recommended dose is 1.25 mg (0.05 mL) near-monthly into affected eyes during the first 12 months, with fewer injections needed in subsequent years. Maximum of 12 doses per year per eye.   |
|                 |                          | Neovascular age-related macular degeneration   |   |
|                 |                          | Neovascular glaucoma   |   |
|                 |                          | Neovascularization of the iris (rubeosis iridis)   |   |
|                 |                          | Proliferative diabetic retinopathy   |   |
|                 |                          | Type I retinopathy of prematurity  |   |
|                 |                          | Oncology   |   |
| 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           | brolicizumab             | Neovascular age-related macular degeneration   | The recommended dose is 6 mg (0.05 mL) into affected eye(s) once monthly (approximately every 25 to 31 days) for the first 3 doses, then 6 mg every 8 to 12 weeks thereafter. Maximum of 12 doses per year per eye.   |
|                 |                          | 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. Maximum of 12 doses per year per eye.  |
| 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. Maximum of 12 doses per year per eye. |
|                 |                          | 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). Maximum of 12 doses per year per eye.   |
|                 |                          | 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.   |

| Medication Name   |                        | Diagnosis   | Maximum Frequency   |
|-------------------|------------------------|---|---|
| Brand             | Generic                |   |   |
| 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. |
| 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). Maximum of 12 doses per year per eye.                                   |
|                   |                        | Diabetic retinopathy  |   |
|                   |                        | Macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO)                  | The recommended dose is 2 mg (0.05 mL) once every 4 weeks. Maximum of 12 doses per year per eye.  |
|                   |                        | Neovascular age-related macular degeneration  | The recommended dose is 2 mg (0.05 mL) into affected eye(s) every 4 weeks (approximately every 28 days, monthly) for the first 12 weeks (3 months), followed by 2 mg once every 8 weeks (2 months). Maximum of 12 doses per year per eye.                       |
| 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.  |

| Medication Name                              |   | Diagnosis  | Maximum Frequency  |
|--|---|--|--|
| Brand  | Generic   |  |  |
| 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.   |
|  |   | Tumor necrosis factor receptor associated periodic syndrome (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.   |
| Avsola<br>Inflectra<br>Remicade<br>Renflexis | infliximab-axxq<br>infliximab-dyyb<br>infliximab<br>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.   |

| Medication Name |                    | Diagnosis  | Maximum Frequency   |
|-----------------|--------------------|--|---|
| Brand           | Generic            |  |   |
| Lucentis        | ranibizumab        | Choroidal neovascularization secondary to pathologic myopia, angioid streaks/pseudoxanthoma elasticum, or ocular histoplasmosis syndrome | The recommended dose is 0.5 mg to affected eye(s) once a month (approximately every 28 days) for up to 3 months. May be retreated if necessary. Maximum of 12 doses per year per eye.   |
|                 |                    | Diabetic macular edema   | The recommended dose is 0.3 mg to affected eye(s) once a month (approximately every 28 days). Maximum of 12 doses per year per eye.   |
|                 |                    | Diabetic retinopathy   |   |
|                 |                    | Macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO)                                 | The recommended dose is 0.5 mg to affected eye(s) once a month (approximately every 28 days). Maximum of 12 doses per year per eye.   |
|                 |                    | Neovascular age-related macular degeneration   | The recommended dose is 0.5 mg to affected eye(s) once a month (approximately every 28 days). Treatment may be reduced to 3 once monthly doses, followed by an average of 4 to 5 injections over the subsequent 9 months. Maximum of 12 doses per year per eye. |
| 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.  |
| 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.<br>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.  |

| Medication Name    |                            | Diagnosis  | Maximum Frequency   |
|--------------------|----------------------------|--|---|
| Brand              | Generic                    |  |   |
| 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, NMOSD, PNH   | Administered once weekly for 5 doses, then every 2 weeks thereafter.  |
| Spevigo            | spesolimab-sbzo            | 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.  |
| Stelara<br>Stelara | ustekinumab<br>ustekinumab | Psoriasis, psoriatic arthritis   | Administered subcutaneously – initially and 4 weeks later, then every 12 weeks thereafter.  |
|                    |                            | Crohn's disease<br>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   | 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. Maximum of 12 doses per year per eye.   |
|                 |  | 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. Maximum of 12 doses per year per eye. |
| 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 | Myasthenia gravis                            | 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 serum total 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.   |

## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service.

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

| HCPCS Code | Description   |
|------------|---|
| J0129      | Injection, abatacept, 10 mg (Code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug self-administered) |
| J0222      | Injection, patisiran, 0.1 mg  |
| 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, 1 mg  |
| J3489      | Injection, zoledronic acid, 1 mg  |
| J7170      | Injection, emicizumab-kxwh, 0.5 mg  |
| J9022      | Injection, atezolizumab, 10 mg  |
| J9023      | Injection, avelumab, 10 mg  |

| HCPCS Code | Description   |
|------------|---|
| 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, 19iabnii), 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 (Fylneta), 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   |

| National Drug Code  | Description   |
|---|---|
| 70121-1755-07   | Alymsys 400mg/16mL vial                                   |
| 71336-1003-01   | Amvuttra 25 mg/0.5 mL PFS                                 |
| 50242-0060-01<br>50242-0060-10  | Avastin 100 mg/4 mL vial                                  |
| 50242-0061-01<br>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<br>00143-9750-01<br>00591-3221-26   | Testosterone enanthate 200 mg/mL vial                     |
| 00517-1830-01<br>52536-0625-10<br>52536-0625-01<br>64980-0467-99<br>69097-0802-32<br>69097-0802-37<br>00574-0827-01<br>76519-1210-00<br>00009-0086-01<br>00009-0417-01<br>00009-0520-01<br>69097-0536-37<br>69097-0537-31<br>69097-0537-37<br>50090-0330-00<br>00409-6562-02<br>00409-6562-22<br>00143-9659-01<br>62756-0017-40<br>62756-0016-40<br>00409-6557-01<br>00409-6562-01<br>00409-6562-20<br>76420-0650-01<br>00591-4128-79<br>00009-0085-10<br>00009-0086-10<br>00574-0827-10<br>00009-0520-10 | Depo-Testosterone (testosterone cypionate) 200 mg/mL vial |

| National Drug Code  | Description   |
|---|---|
| 00009-0347-02<br>62756-0015-40<br>00143-9726-01<br>00009-0417-02<br>63874-1061-01<br>00574-0820-01<br>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                                       |
| 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<br>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<br>00006-3029-02  | Keytruda 50 mg vial                                       |
| 00006-3026-01<br>00006-3026-02<br>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                                       |

| National Drug Code             | Description                                  |
|--------------------------------|--|
| 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<br>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                       |
| 00003-2187-10<br>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<br>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<br>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<br>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                     |
| 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                      |

| National Drug Code  | Description   |
|---|---|
| 50242-0918-01   | Tecentriq 840mg/14mL vial                           |
| 50242-0917-01   | Tecentriq 1200mg/20mL vial                          |
| 66887-0004-01<br>66887-0004-10<br>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<br>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                       |
| 32228-0011-01<br>32228-0011-02  | Vegzelma 100 mg/4 mL vial                           |
| 32228-0011-03<br>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                            |
| 50242-0215-01   | Xolair 150 mg PFS                                   |
| 50242-0214-01   | Xolair 75 mg PFS                                    |
| 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<br>23155-0186-31<br>25021-0826-67<br>25021-0826-82  | Zoledronic Acid 4 mg/100 mL infusion                |
| 70860-0210-51   | Zoledronic Acid 4 mg/100 mL vial                    |
| 00409-4215-01<br>00409-4215-05<br>16714-0815-01<br>16729-0242-31<br>23155-0170-31<br>25021-0801-66<br>43598-0330-11<br>51991-0065-98<br>54288-0100-01 | Zoledronic Acid 4 mg/5 mL vial                      |

| National Drug Code  | Description                          |
|---|--------------------------------------|
| 55111-0685-07<br>55150-0266-05<br>63323-0961-98<br>67457-0390-54<br>68001-0366-22<br>68001-0366-25                  | Zoledronic Acid 4 mg/5 mL vial       |
| 00409-4228-01<br>25021-0830-82<br>67457-0794-10<br>70860-0802-82  | Zoledronic Acid 5 mg/100 mL infusion |
| 00078-0435-61<br>25021-0830-82<br>43598-0331-11<br>51991-0064-98<br>55111-0688-52<br>63323-0966-00<br>67457-0619-10 | Zoledronic Acid 5 mg/100 mL vial     |

## Benefit Considerations

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

## Clinical Evidence

The aforementioned pharmaceuticals all have dosing parameters that support a maximum dosage per body weight or body surface area or a set maximal dosage independent of patient body size. These maximum doses are product-specific, and in some cases, disease state-specific and are defined in the U.S. Food and Drug Administration (FDA) approved product prescribing information and/or in national compendia and other peer reviewed resources. This policy creates an upper dose limit based on the clinical evidence and the 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.

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26. Opdivo [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company, May 2022.
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## Policy History/Revision Information

| Date       | Summary of Changes   |
|------------|--|
| 06/01/2024 | <p><b>Coverage Rationale</b></p> <p><b>Maximum Allowed Frequencies</b></p> <p>Xolair (omalizumab)</p> <ul style="list-style-type: none"> <li>• Updated the maximum allowed frequency for the diagnosis of nasal polyps; replaced “administered once every 2 or 4 weeks, depending on body weight and IgE levels” with “administered once every 2 or 4 weeks, depending on body weight and <i>serum total</i> IgE levels”</li> <li>• Added language to indicate the maximum allowed frequency for the diagnosis of IgE-mediated food allergy is administration once every 2 or 4 weeks, depending on body weight and serum total IgE levels</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> <li>• Archived previous policy version 2024D0034AL</li> </ul> |

## Instructions for Use

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

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

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