MEDICARE PART B STEP THERAPY PROGRAMS

Policy Number: IAP.001.05
Effective Date: January 1, 2021

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INSTRUCTIONS FOR USE

This Medical Benefit Injectable Policy is applicable to most UnitedHealthcare Medicare Advantage plans offered by UnitedHealthcare and its affiliates. See the Plan Exceptions section of this policy.

This Medical Benefit Injectable Policy is provided for informational purposes only and does not constitute medical advice. Treating physicians and health care providers are solely responsible for making any decisions about medical care.

Each benefit plan contains its own provisions for coverage, limitations and exclusions as stated in the member’s Evidence of Coverage (EOC)/Summary of Benefits (SB). If there is a discrepancy between this policy and the member’s EOC/SB, the member’s EOC/SB provision(s) will govern.

In the event of a conflict between this policy and Medicare National Coverage Determinations (NCD), Local Coverage Determinations (LCD) and Medicare manuals, the Medicare NCD/LCD/manual will apply.

Each class of medical benefit injectable covered under Medicare Part B referenced below includes preferred drugs(s)/product(s) that do not require prior authorization. Prior authorization for a non-preferred drug/product will generally require history of use of a preferred drug/product within the same medical benefit injectable class, among other criteria. If a provider administers a non-preferred drug/product without obtaining prior authorization, United may deny claims for the non-preferred drug/product. The classes of medical benefit injectables that include non-preferred drug(s)/product(s) subject to prior authorization, and preferred drug(s)/product(s), are listed in this policy.

BENEFIT CONSIDERATIONS

Before using this policy, check the member’s EOC/SB and any federal or state mandates, if applicable.

Experimental and investigational procedures, items and medications are not covered. Investigational Device Exemption Studies (IDE) are only covered when Medicare requirements are met. For coverage requirements, refer to the Experimental Procedures and Items, Investigational Devices and Clinical Trials Coverage Summary.

COVERAGE RATIONALE

This policy supplements Medicare NCDs, LCDs, and manuals for the purpose of determining coverage under Medicare Part B medical benefits. This policy implements a prior authorization requirement for prescriptions or administrations of medical benefit injectables only. A member cannot be required under this policy to change a current drug/product. For the purposes of this policy, a current drug/product means the member has a paid claim for the drug/product within the past 365 days. For example, a new plan member currently using a particular drug/product will not be required to switch to the preferred drug/product upon enrollment. Similarly, an existing member currently using a particular drug/product will not be required to change drugs/products in the event this policy is updated.

This policy applies to step therapy for the following drugs/products:

- **Erythropoietic Agents** (Aranesp, Procrit, Retacrit)
- **Infliximab** (Avsola, Inflectra, Remicade, Renflexis)
Colony Stimulating Factors
- Short Acting (Granix, Neupogen, Nivestym, Zaxia)
- Long Acting (Fulphila, Neulasta, Nyvepra, Udenyca, Ziextenzo)

Hyaluronic Acid Polymers (Durolane, Euflexxa, Gel-One, Gelsyn-3, Genvisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz, Supartz Fx, Synojoynt, Synvisc, Synvisc-One, Triluron, Trivisc, Visco-3)

Intravitreal Vascular Endothelial Growth Factor (VEGF) Inhibitors (Compounded Avastin, Beovu, Eylea, Lucentis, Macugen)

A non-preferred drug/product must satisfy the following criteria. If a provider administers a non-preferred drug/product without obtaining prior authorization, UnitedHealthcare may deny claims for the non-preferred drug/product.

I. Erythropoietic Agents (Aranesp, Procrit, Retacrit)

Applicable Drugs
- Preferred drug(s): Retacrit
- Non-preferred drug(s): Aranesp, Procrit

Non-Preferred Product Step Therapy Criteria
Aranesp or Procrit may be covered when the criteria listed under Sections A., B., or C. are satisfied:

A. History of use of Retacrit resulting in minimal clinical response to therapy

OR

B. History of intolerance or adverse event to Retacrit

OR

C. Continuation of prior therapy within the past 365 days.

Applicable HCPCS Codes

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J0881</td>
<td>Injection, darbepoetin alfa, (Aranesp) 1 mcg (non-ESRD use)</td>
</tr>
<tr>
<td>J0885</td>
<td>Injection, epoetin alfa, (Procrit) (for non-ESRD use), 1000 units</td>
</tr>
<tr>
<td>Q5106*</td>
<td>Injection, epoetin alfa, biosimilar, (Retacrit) (for non-ESRD use), 1000 units</td>
</tr>
</tbody>
</table>

*Preferred Drug(s)/Product(s)

II. Infliximab (Avsola, Inflectra, Remicade, Renflexis)

Applicable Drugs
- Preferred drug(s): Inflectra, Renflexis
- Non-preferred drug(s): Remicade, Avsola

Non-Preferred Product Step Therapy Criteria
Remicade or Avsola may be covered when the criteria listed under Sections A., B., or C. are satisfied:

A. Trial of at least 14 weeks of Inflectra or Renflexis resulting in minimal clinical response to therapy and residual disease activity2,3

OR

B. History of intolerance or adverse event to Inflectra or Renflexis

OR

C. Continuation of prior therapy within the past 365 days.

Applicable HCPCS Codes

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J1745</td>
<td>Injection, infliximab, (Remicade), 10 mg</td>
</tr>
<tr>
<td>Q5103*</td>
<td>Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg</td>
</tr>
<tr>
<td>Q5104*</td>
<td>Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg</td>
</tr>
<tr>
<td>Q5121</td>
<td>Injection, infliximab-axxq, biosimilar, (Avsola), 10mg</td>
</tr>
</tbody>
</table>

*Preferred Drug(s)/Product(s)
III. Colony Stimulating Factors

Short-Acting (Granix, Neupogen, Nivestym, Zarxio)

Applicable Drugs
- Preferred drug(s): Zarxio
- Non-preferred drug(s): Granix, Neupogen, Nivestym

Non-Preferred Product Step Therapy Criteria

Granix, Neupogen, or Nivestym may be covered when the criteria listed Sections A., B., or C. are satisfied:

A. History of use of Zarxio resulting in minimal clinical response to therapy

OR

B. History of intolerance or adverse event to Zarxio

OR

C. Continuation of prior therapy within the past 365 days.

Applicable HCPCS Codes

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J1442</td>
<td>Injection, filgrastim (G-CSF), (Neupogen) excludes biosimilars, 1 mcg</td>
</tr>
<tr>
<td>J1447</td>
<td>Injection, tbo-filgrastim, (Granix) 1 microgram</td>
</tr>
<tr>
<td>Q5101*</td>
<td>Injection, filgrastim-sndz, biosimilar, (Zarxio) 1 microgram</td>
</tr>
<tr>
<td>Q5110</td>
<td>Injection, filgrastim-aafi, biosimilar, (Nivestym), 1 microgram</td>
</tr>
</tbody>
</table>

*Preferred Drug(s)/Product(s)

Long-Acting (Neulasta, Udenyca, Fulphila, Ziextenzo, Nyvepria)

Applicable Drugs
- Preferred drug(s): Neulasta, Udenyca
- Non-preferred drug(s): Fulphila, Nyvepria, Ziextenzo,

Non-Preferred Product Step Therapy Criteria

Fulphila, Nyvepria, or Ziextenzo may be covered when the criteria listed under Sections A., B., or C. are satisfied:

A. History of use of Neulasta and Udenyca resulting in minimal clinical response to therapy

OR

B. History of intolerance or adverse event to Neulasta and Udenyca

OR

C. Continuation of prior therapy within the past 365 days.

Applicable HCPCS Codes

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J2505*</td>
<td>Injection, pegfilgrastim, (Neulasta) 6 mg</td>
</tr>
<tr>
<td>Q5108</td>
<td>Injection, pegfilgrastim-jmdb, biosimilar, (Fulphila), 0.5 mg</td>
</tr>
<tr>
<td>Q5111*</td>
<td>Injection, pegfilgrastim-cbqv, biosimilar, (Udenyca), 0.5 mg</td>
</tr>
<tr>
<td>Q5122</td>
<td>Injection, pegfilgrastim-apgf, biosimilar, (Nyvepria), 0.5 mg</td>
</tr>
</tbody>
</table>

*Preferred Drug(s)/Product(s)

IV. Hyaluronic Acid Polymers (Durolane, Euflexxa, Gel-One, Gelsyn-3, Genvisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz, Supartz Fx, Synojoynt, Synvinc, Synvisc-One, Visco-3, Triluron, TriVisc)

Applicable Products
- Preferred product(s): Durolane, Gelsyn-3, Synvisc, Synvisc-One
- Non-preferred product(s): Euflexxa, Gel-One, Genvisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz, Supartz Fx, Synojoynt, Triluron, TriVisc, Visco-3
**Non-Preferred Product Step Therapy Criteria**

**Euflexxa, Gel-One, Genvisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz, Supartz FX, Synojoynt, Triluron, TriVisc, or Visco-3** may be covered when the criteria listed under Sections A., B., or C. are satisfied:

A. Trial and failure of all of the following: *Durolane, Gelsyn-3, and Synvisc/Synvisc-One*, resulting in minimal clinical response to therapy

OR

B. History of intolerance or adverse event to all of the following: *Durolane, Gelsyn-3, and Synvisc/Synvisc-One*

OR

C. Continuation of prior therapy within the past 365 days.

**Applicable HCPCS Codes**

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>J7318*</td>
<td>Hyaluronan or derivative, Durolane, for intra-articular injection, 1 mg</td>
</tr>
<tr>
<td>J7320</td>
<td>Hyaluronan or derivative, GenVisc 850, for intra-articular injection, 1 mg</td>
</tr>
<tr>
<td>J7321</td>
<td>Hyaluronan or derivative, Hylgan or Supartz, for intra-articular injection, per dose</td>
</tr>
<tr>
<td>J7322</td>
<td>Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg</td>
</tr>
<tr>
<td>J7323</td>
<td>Hyaluronan or derivative, Euflexxa, for intra-articular injection, per dose</td>
</tr>
<tr>
<td>J7324</td>
<td>Hyaluronan or derivative, Orthovisc, for intra-articular injection, per dose</td>
</tr>
<tr>
<td>J7325*</td>
<td>Hyaluronan or derivative, Synvisc or Synvisc-One, for intra-articular injection, 1 mg</td>
</tr>
<tr>
<td>J7326</td>
<td>Hyaluronan or derivative, Gel-One, for intra-articular injection, per dose</td>
</tr>
<tr>
<td>J7327</td>
<td>Hyaluronan or derivative, Monovisc, for intra-articular injection, per dose</td>
</tr>
<tr>
<td>J7328*</td>
<td>Hyaluronan or derivative, Gelsyn-3, for intra-articular injection, 0.1 mg</td>
</tr>
<tr>
<td>J7329</td>
<td>Hyaluronan or derivative, TriVisc, for intra-articular injection, 1 mg</td>
</tr>
<tr>
<td>J7331</td>
<td>Hyaluronan or derivative, Synojoynt, for intra-articular injection, 1mg</td>
</tr>
<tr>
<td>J7332</td>
<td>Hyaluronan or derivative, Triluron, for intra-articular injection, 1mg</td>
</tr>
<tr>
<td>J7333</td>
<td>Hyaluronan or derivative, Visco-3 for intra-articular injection per dose</td>
</tr>
</tbody>
</table>

*Preferred Drug(s)/Product(s)

**V. Intravitreal Vascular Endothelial Growth Factor (VEGF) Inhibitors**

**Applicable Drugs**

- Preferred drug(s): **Compounded Avastin (bevacizumab)**
- Non-preferred drug(s): Beovu (brolucizumab-dbll), Eylea (aflibercept), Lucentis (ranibizumab), Macugen (pegaptanib)

**Non-Preferred Product Step Therapy Criteria**

**Eylea, Beovu, Lucentis, or Macugen**, when prescribed for Age Related Macular Degeneration, may be covered when the criteria listed under Sections A. or B. are satisfied:

A. **One** of the following:
   1. History of a trial of at least 3 doses, resulting in minimal clinical response to compounded Avastin (bevacizumab) **OR**
   2. History of contraindication or adverse event(s) to compounded Avastin (bevacizumab) **OR**

B. Continuation of prior therapy within the past 365 days.

**Applicable HCPCS Codes**

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9257</td>
<td>Injection, bevacizumab (Avastin), 0.25mg *</td>
</tr>
<tr>
<td>J0178</td>
<td>Aflibercept injection (Eylea)</td>
</tr>
<tr>
<td>J0179</td>
<td>Brolucizumab-dbll, injection (Beovu)</td>
</tr>
</tbody>
</table>
 HCPCS Code | Description |
---|---|
 J2503 | Pegaptanib Injection (Macugen) |
 J2778 | Ranibizumab injection (Lucentis) |
 J7999 | Compounded drug, not otherwise classified * |
 J9035 | Injection, bevacizumab (Avastin), 10mg* |

*Preferred Product(s)

**BACKGROUND/DESCRIPTION OF SERVICES**

Effective January 1, 2020, certain classes of medical benefit injectables covered under Medicare Part B will include non-preferred therapies that require prior authorization. Each class of medical injectables will include preferred therapies that do not require prior authorization. Prior authorization for a non-preferred therapy will generally require history of use of a preferred therapy within the same medical benefit injectable class, among other criteria.

This prior authorization requirement will apply to some, but not all, Medicare Advantage Plans. See the Plan Exceptions section of this policy.

If a provider administers a non-preferred therapy without obtaining prior authorization, United may deny claims for the non-preferred therapy.

**CLASSES OF MEDICAL INJECTABLES**

Three classes of medical benefit injectables (Erythropoietic Agents, Colony Stimulating Factors, and Infliximab) covered under Medicare Part B that will include preferred and non-preferred drugs/products are biosimilar products.

A biosimilar product is a biologic product that is approved based on demonstrating that it is highly similar to a FDA-approved biologic product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product.

The classes of medical benefit injectables covered under Medicare Part B that include non-preferred drugs/products subject to prior authorization, and preferred drugs/products, are listed in this policy.

**PLAN EXCEPTIONS**

<table>
<thead>
<tr>
<th>Plan Type</th>
<th>Excluded Plans</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare Advantage</td>
<td>All MA plans in the state of California; Erickson Advantage plans; People’s plans in Louisiana; PFFS, UnitedHealthcare Connected plans; UnitedHealthcare Dual Complete plans in New Jersey, Tennessee and Arizona; and UnitedHealthcare Senior Care Options in Massachusetts.</td>
</tr>
<tr>
<td>Employer Group Medicare Advantage</td>
<td>Group plans excluded from Step therapy are the following:</td>
</tr>
<tr>
<td></td>
<td>• All Group HMO plans</td>
</tr>
<tr>
<td></td>
<td>• Select Group PPO plans: Navistar, Johnson &amp; Johnson, Bristol-Myers Squibb, Verizon</td>
</tr>
</tbody>
</table>

**REFERENCES**

1. For "Highlights of Prescribing information" (Retacrit) see: [https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125545s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125545s000lbl.pdf)
2. For “Highlights of Prescribing Information” (Renflexis) see: [https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761054orig1s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761054orig1s000lbl.pdf)
3. For "Highlights of Prescribing Information" (Inflectra) see [https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/125544s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/125544s000lbl.pdf)
4. For “Highlights of Prescribing information” (Avsola) see [https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761086s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761086s000lbl.pdf)
5. For "Highlights of Prescribing Information” (Udenyca) see: [https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/761039s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/761039s000lbl.pdf)
6. For “Highlights of Prescribing Information” (Zarxio) see: [https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125553lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125553lbl.pdf)
For “Highlights of Prescribing Information” (Fulphila) see: [https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/761075s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/761075s000lbl.pdf)

For “Highlights of Prescribing Information” (Nivestym) see: [https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/761080s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/761080s000lbl.pdf)

For “Highlights of Prescribing Information” (Ziextenzo) see: [https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761045lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761045lbl.pdf)

For “Highlights of Prescribing Information” (Nyvepria) see: [https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761111lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761111lbl.pdf)

Medicare does not have a National Coverage Determination (NCD) for intra-articular injections of sodium hyaluronate. Local Coverage Determinations (LCDs) exist. See: [medady-coverage-sum/medications-drugs-outpatient-partb.pdf](https://www.cms.gov/Medicare/HealthishP/history-revision-information)

Medicare does not have a National Coverage Determination (NCD) for the use of vascular endothelial growth factor (VEGF) inhibitors; such as Avastin® (bevacizumab), Eylea™ (aflibercept), Lucentis® (ranibizumab) and Macugen® (pegaptanib). Local Coverage Determinations (LCDs)/ Local Coverage Articles (LCAs) exist. See: [medady-coverage-sum/medications-drugs-outpatient-partb.pdf](https://www.cms.gov/Medicare/HealthishP/history-revision-information)

Avastin (bevacizumab) prescribing information. Genentech, Inc. 2004

Lucentis (ranibizumab) prescribing information. Genentech, Inc. 2006

Eylea (aflibercept) prescribing information. Regeneron Pharmaceuticals, Inc.

Beovu (brolucizumab) prescribing information. Novartis Pharmaceuticals Corporation


### POLICY HISTORY/REVISION INFORMATION

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
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</table>
| 01/01/2021| **Coverage Rationale**<br>• Removed criteria requiring physician attestation for use of non-preferred products for:<br>  o Erythropoietic agents<br>  o Infliximab products<br>  o Colony stimulating factors<br>  o Hyaluronic acid polymers<br>  
**Intravitreal Vascular Endothelial Growth Factor (VEGF) Inhibitors** (new to policy)<br>• Added list of:<br>  o Preferred drug(s): Compounded Avastin (bevacizumab)<br>  o Non-preferred drug(s): Beovu (brolucizumab-dbll), Eylea (aflibercept), |
<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
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</thead>
<tbody>
<tr>
<td></td>
<td><strong>Lucentis (ranibizumab), Macugen (pegaptanib); refer to the <a href="#">Step Therapy Criteria</a></strong></td>
</tr>
<tr>
<td></td>
<td>• Added list of applicable HCPCS codes: C9257, J0178, J0179, J2503, J2778, J7999, and J9035</td>
</tr>
<tr>
<td></td>
<td><strong>Colony Stimulating Factors: Long-Acting (Neulasta, Udenyca, Fulphila, Ziextenzo)</strong></td>
</tr>
<tr>
<td></td>
<td>• Updated list of non-preferred colony stimulating factors; added Nyprevia</td>
</tr>
<tr>
<td></td>
<td>• Added HCPCS code Q5122</td>
</tr>
<tr>
<td></td>
<td><strong>Supporting Information</strong></td>
</tr>
<tr>
<td></td>
<td>• Updated References section to reflect the most current information</td>
</tr>
<tr>
<td></td>
<td>• Archived previous policy version IAP.001.04</td>
</tr>
</tbody>
</table>