UnitedHealthcare Medicare Part B Step Therapy Programs

**MEDICARE PART B STEP THERAPY PROGRAMS**

**Policy Number:** IAP.001.01  
**Effective Date:** January 1, 2019

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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, please 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 120 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** (Inflectra, Remicade, Renflexis)
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 used when all of the criteria listed under ONE of the following sections A., B., or C. are satisfied:

A. **All** of the following:
   1. History of use of Retacrit resulting in minimal clinical response to therapy; and
   2. Physician attests that in their clinical opinion the clinical response would be expected to be superior with Aranesp or Procrit than with Retacrit.

   **OR**

B. **All** of the following:
   1. History of intolerance or adverse event to Retacrit;
   2. Physician attests that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Aranesp or Procrit; and
   3. For patients, who are unable to tolerate Retacrit or in the rare instance that Retacrit is contraindicated for a patient, documentation is required that clearly indicates the reason that the patient cannot use Retacrit.

   **OR**

C. Continuation of prior therapy within the past 120 days.

**Applicable HCPCS Codes**

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<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 Product(s)

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

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

**Non-Preferred Product Step Therapy Criteria**
Remicade may be used when all of the criteria listed under ONE of the following sections A., B., or C. are satisfied:

A. **All** of the following:
   1. Trial of at least 14 weeks of Inflectra or Renflexis resulting in minimal clinical response to therapy and residual disease activity\(^{2,3}\); and
   2. Physician attests that in their clinical opinion the clinical response would be expected to be superior with Remicade than with Inflectra or Renflexis.

   **OR**

B. **All** of the following:
   1. History of intolerance or adverse event to Inflectra or Renflexis; and
   2. Physician attests that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Remicade; and
   3. For patients, who are unable to tolerate Inflectra or Renflexis or in the rare instance that the preferred products above are contraindicated for a patient, documentation is required that clearly indicates the reason that the patient cannot take one of the above preferred products.
OR
C. Continuation of prior therapy within the past 120 days.

**Applicable HCPCS Codes**

<table>
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<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<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>
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</table>

*Preferred Product(s)

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

**Applicable Products**

- Preferred product(s): Durolane, Gelsyn-3, Synvisc, Synvisc-One
- Non-preferred product(s): Euflexxa, Gel-One, Genvisc 850, Hyalgan, Hymovis, Orthovisc, Monovisc, Supartz, Supartz FX, TriVisc, Visco-3

**Non-Preferred Product Step Therapy Criteria**

Euflexxa, Gel-One, Genvisc 850, Hyalgan, Hymovis, Orthovisc, Monovisc, Supartz, Supartz FX, TriVisc, or Visco-3 may be used when all of the criteria listed under ONE of the following sections A., B., or C. are satisfied:

A. All of the following:
   1. Trial and failure of all of the following: Durolane, Gelsyn-3, and Synvisc/Synvisc-One, resulting in minimal clinical response to therapy; and
   2. Physician attests that in their clinical opinion the clinical response would be expected to be superior with the non-preferred agent than with all of the following: Durolane, Gelsyn-3, and Synvisc/Synvisc-One.

OR

B. All of the following:
   1. History of intolerance or adverse event to all of the following: Durolane, Gelsyn-3, and Synvisc/Synvisc-One; and
   2. Physician attests that in their clinical opinion the same intolerance or adverse event would not be expected to occur with the non-preferred agent; and
   3. For patients, who are unable to tolerate Durolane, Gelsyn-3, and Synvisc/Synvisc-One, or in the rare instance that the above preferred products are contraindicated for a patient, documentation is required that clearly indicates the reason that the patient cannot use all of the above preferred products.

OR

C. Continuation of prior therapy within the past 120 days.

**Applicable HCPCS Codes**

<table>
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<tr>
<th>HCPCS Code</th>
<th>Description</th>
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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, Hyalgan, Supartz or Visco-3, 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>
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<tr>
<td>J7324</td>
<td>Hyaluronan or derivative, Orthovisc, for intra-articular injection, per dose</td>
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<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>
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<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>
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</tbody>
</table>

*Preferred Product(s)
BACKGROUND/DESCRIPTION OF SERVICES

Effective January 1, 2019, 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 required 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

Two classes of medical benefit injectables (Erythropoietic Agents 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>
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<tr>
<th>Plan Type</th>
<th>Excluded Plans</th>
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<tbody>
<tr>
<td>Medicare Advantage</td>
<td>All plans in these states: Arizona, California, Colorado, Hawaii, Nevada, Washington</td>
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<tr>
<td></td>
<td>Employer group Medicare Advantage plans nationwide</td>
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<tr>
<td></td>
<td>Erickson Advantage plans</td>
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<tr>
<td></td>
<td>UnitedHealthcare Connected plans</td>
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<tr>
<td>Medicare Advantage DSNP</td>
<td>All plans in these states: New Jersey, Tennessee, and Senior Care Options in Massachusetts</td>
</tr>
</tbody>
</table>

REFERENCES

1. For “Highlights of Prescribing information” (Retacrit) see: 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
3. For “Highlights of Prescribing Information” (Inflectra) see: https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/125544s000lbl.pdf

POLICY HISTORY/REVISION INFORMATION

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<th>Date</th>
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