MEDICARE PART B STEP THERAPY PROGRAMS

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

Table of Contents **Page**

Medicare Advantage Coverage Summary

- Medications/Drugs (Outpatient/Part B)

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, Zarxio)
  - Long Acting (Fulphila, Neulasta, Nyvepria, 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

HCPCS Code	Description
J0881	Injection, darbepoetin alfa, (Aranesp) 1 mcg (non-ESRD use)
J0885	Injection, epoetin alfa, (Procrit) (for non-ESRD use), 1000 units
Q5106*	Injection, epoetin alfa, biosimilar, (Retacrit) (for non-ESRD use), 1000 units

**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 activity[2,3]

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

J1745	Injection, infliximab, (Remicade), 10 mg
Q5103*	Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg
Q5104*	Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg
Q5121	Injection, infliximab-axxq, biosimilar, (Avsola), 10mg

**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

HCPCS Code	Description
J1442	Injection, filgrastim (G-CSF), (Neupogen) excludes biosimilars, 1 mcg
J1447	Injection, tbo-filgrastim, (Granix)1 microgram
Q5101*	Injection, filgrastim-sndz, biosimilar, (Zarxio) 1 microgram
Q5110	Injection, filgrastim-aafi, biosimilar,(Nivestym), 1 microgram

**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

HCPCS Code	Description
Q5120	Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo) 0.5mg
J2505*	Injection, pegfilgrastim, (Neulasta) 6 mg
Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (Fulphila), 0.5 mg
Q5111*	Injection, pegfilgrastim-cbqv, biosimilar, (Udenyca), 0.5 mg
Q5122	Injection, pegfilgrastim-apgf, biosimilar, (Nyvepria), 0.5mg

**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, Synvisc, 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

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

**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

HCPCS Code	Description
C9257	Injection, bevacizumab (Avastin), 0.25mg *
J0178	Afibercept injection (Eylea)
J0179	Brolucizumab-dbll, injection (Beovu)

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 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

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

Plan Type	Excluded Plans
Non-Employer Group Medicare Advantage	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.
Employer Group Medicare Advantage	Group plans excluded from Step therapy are the following: • All Group HMO plans • Select Group PPO plans: Navistar, Johnson & Johnson, Bristol-Myers Squibb, Verizon

REFERENCES

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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
4. For "Highlights of Prescribing information" (Avsola) see 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
6. For "Highlights of Prescribing Information" (Zarxio) see: https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125553lbl.pdf

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9. For "Highlights of Prescribing Information" (Ziextenzo) see: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761045lbl.pdf
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12. 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: medadv-coverage-sum/medications-drugs-outpatient-partb.pdf
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23. https://www.federalregister.gov/documents/2019/05/23/2019-10521/modernizing-part-d-and-medicare-advantage-to-lower-drug-prices-and-reduce-out-of-pocket-expenses
24. For CMS Memorandum titled "Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage", dated August 7, 2018 see: https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description

01/01/2021	**Coverage Rationale**
	• Removed criteria requiring physician attestation for use of non-preferred products for:
	  ○ Erythropoietic agents
	  ○ Infliximab products
	  ○ Colony stimulating factors
	  ○ Hyaluronic acid polymers
	Intravitreal Vascular Endothelial Growth Factor (VEGF) Inhibitors (new to policy)
	• Added list of:
	  ○ Preferred drug(s): Compounded Avastin (bevacizumab)
	  ○ Non-preferred drug(s): Beovu (brolucizumab-dbll), Eylea (aflibercept),

Date	Action/Description
	Lucentis (ranibizumab), Macugen (pegaptanib); refer to the Step Therapy Criteria • Added list of applicable HCPCS codes: C9257, J0178, J0179, J2503, J2778, J7999, and J9035 ***Colony Stimulating Factors: Long-Acting (Neulasta, Udenyca, Fulphila, Ziextenzo)*** • Updated lit of non-prefered colony simulating factors; added Nyprevia • Added HCPCS code Q5122 **Supporting Information** • Updated References section to reflect the most current information • Archived previous policy version IAP.001.04