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## Medicare Part B Step therapy MB2011

**This policy is specific to The Health Plan Medicare products.**

| | |
|---|---|
| **Covered Service:** | Yes |
| **Prior Authorization Required:** | Yes |
| **Additional Information:** | 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 class of medical benefit drugs 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 drug class, among other criteria. If a provider administers a non-preferred drug/product without obtaining prior authorization, The Healthplan may deny claims for the non-preferred drug/product. The classes of medical benefit drugs that include nonpreferred drug(s)/product(s) subject to prior authorization, and preferred drug(s)/product(s), are listed in this policy. |

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 drugs 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.

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

### Health Plan Approved Criteria:

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

A. Erythropoietic Agents (Procrit, Retacrit)

A. Applicable Drugs

i. Preferred drug(s): Retacrit

ii. Non-preferred drug(s): Procrit

**Non-Preferred Product Step Therapy Criteria**

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 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 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 365 days.

Applicable HCPCS Codes

| HCPCS Code | Description |
|---|---|
| J0885 | Injection, epoetin alfa, (Procrit) (for non-ESRD use), 1000 units |
| Q5106* | Injection, epoetin alfa, biosimilar, (Retacrit) (for non-ESRD use),1000 unit |

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

a. Applicable Drugs

i. Preferred drug(s): Renflexis

ii. Non-preferred drug(s): Remicade, Avsola ,Inflectra

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**Non-Preferred Product Step Therapy Criteria**

Remicade, Inflectra or Avsola 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 Renflexis resulting in minimal clinical response to therapy and residual disease activity; and
2. Physician attests that in their clinical opinion the clinical response would be expected to be superior with Remicade,Avsola or Inflectra than with Renflexis.

OR

B. All of the following:

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

OR

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

| Jcode | Description |
|---|---|
| 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 |

C. Colony Stimulating Factors Short-Acting (Granix, Neupogen, Nivestym, Zarxio)
   A. Applicable Drugs
      i. Preferred drug(s): Zarxio, Nivestym
      ii. Non-preferred drug(s): Granix, Neupogen, Leukine

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**Non-Preferred Product Step Therapy Criteria**

Granix, Leukine or Neupogen may be used when all of the criteria listed under ONE of the following sections A., B., or C. are satisfied:

A. Both of the following:
   1. History of use of Zarxio or Nivestym 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 Neupogen, Leukine or Granix than with Zarxio and Nivestym.

   OR

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

   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 |
| J2820 | Injection, sargramostim (GM-CSF), (Leukine), 50mcg |

D. Colony Stimulating Factors Long-Acting (Neulasta, Udenyca, Fulphila, Ziextenzo)
   a. Applicable Drugs
      i. Preferred drug(s): Udenyca , Fulphila, Ziextenzo
      ii. Non-preferred drug(s): Neulasta

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## Non-Preferred Product Step Therapy Criteria

Neulasta 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 Udenyca,Fulphila or Ziextenzo 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 Neulasta than with Udenyca, Fulphila or Ziextenzo

   OR

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

   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 |

*Preferred Drug(s)/Product(s)

D. 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)
   a. Applicable Products
      i. Preferred product(s): Synvisc-One or Monovisc

ii. Non-preferred product(s):Orthovisc,Durolane, Euflexxa, Gel-One, Genvisc 850, Hyalgan, Hymovis, Orthovisc, Supartz, Supartz FX, Synojoynt, Triluron, TriVisc, Visco-3

**Non-Preferred Product Step Therapy Criteria**

Euflexxa, Gel-One, Genvisc 850, Hyalgan, Hymovis, Orthovisc, Supartz, Supartz FX, Synojoynt, Triluron, 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: Synvisc-One or Monovisc 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 Synvisc – One or Monovisc OR
B. All of the following:

    1. History of intolerance or adverse event to all of the following: Monovisc and 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 Monovisc or SynviscOne and, 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 365 days.

| HCPCS Code | Description |
|---|---|
| J7323 | Hyaluronan or derivative,euflexxa,for intra-articular inj,per dose |
| J7326 | Hyaluronan or derivative,gel-one,for intra-articular inj,per dose |
| J7320 | Hyaluronan or derivative,Genvisc 850,for intra-articular inj,per dose |
| J7321 | Hyaluronan or derivative, hyalgan, supartz, Supartz-FX, for intra-articular injection, per dose |
| J7322 | Hyaluronan or derivative, hymovis, for intra-articular injection, 1 mg |
| J7324 | Hyaluronan or derivative, orthovisc, for intra-articular injection, per dose |

| | |
|---|---|
| J7331 | Hyaluronan or derivative, synojoynt, for intra-articular injection, 1 mg |
| J7332 | Hyaluronan or derivative, triluron, for intra-articular injection, 1 mg |
| J7329 | Hyaluronan or derivative, trivisc, for intra-articular injection, 1 mg |
| J7333 | Hyaluronan or derivative, visco-3, for intra-articular injection, per dose |
| J7327 | Hyaluronan or derivative, monovisc, for intra-articular injection, per dose |
| J7325 | Hyaluronan or derivative, synvisc or synvisc-one, for intra-articular injection, 1 mg |

E. EGFR inhibitors (Avastin, Mvasi, Zirabev)

a. Applicable Drugs

i. Preferred drug(s): Mvasi, Zirabev

ii. Non-preferred drug(s): Avastin

**Non-Preferred Product Step Therapy Criteria**

Avastin 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 Mvasi or Zirabev 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  than with Avastin.

OR

B. All of the following:

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

OR

C. Continuation of prior therapy within the past 365 days

| HCPCS codes | Description |
|---|---|
| J9035 | Injection, bevacizumab, 0.25 mg |
| Q5107 | Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg |
| Q5189 | Injection, bevacizumab-bvzr, biosimilar, (zirabev), 10 mg |

D. CD-20 Directed antibody (Rituxan, Truxima, and Ruxience)

a. Applicable Drugs

iii. Preferred drug(s): Truxima and Ruxience

iv. Non-preferred drug(s): Rituxan

**Non-Preferred Product Step Therapy Criteria**

Rituxan 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 Truxima and Ruxience 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 Rituxan than with Truxima and Ruxience

OR

B. All of the following:

1.History of intolerance or adverse event to Truxima and Ruxience and

2.Physician attests that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Rituxan; and

3. For patients, who are unable to tolerate Truxima and Ruxience or in the rare instance that Truxima and Ruxience is contraindicated for a patient, documentation is required that clearly indicates the reason that the patient cannot use Truxima and Ruxience.

OR

C. Continuation of prior therapy within the past 365 days

| HCPSC | Description |
|---|---|
| J9312 | Injection, rituximab 10 mg and hyaluronidase |
| Q5115 | Injection, rituximab-abbs, biosimilar, (truxima), 10 mg |
| Q5119 | Injection, rituximab-pvvr, biosimilar, (ruxience), 10 mg |

E. HER 2 Expression (Herzuma, Trazimerz, Kanjinti, Ogivri, Herceptin)

a. Applicable Drugs

v. Preferred drug(s): Herzuma, Trazimerz, Kanjinti, Ogivri

vi. Non-preferred drug(s): Herceptin

**Non-Preferred Product Step Therapy Criteria**

Herceptin 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 Herzuma, Trazimerz, Kanjinti, and Ogivri 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 Herceptin than with Herzuma, Trazimerz, Kanjinti, or Ogivri

OR

B. All of the following:

1. History of intolerance or adverse event to Herzuma, Trazimerz, Kanjinti, Ogivri and

2. Physician attests that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Herceptin; and

3. For patients, who are unable to tolerate or in the rare instance that Herzuma, Trazimerz, Kanjinti, and Ogivri is contraindicated for a patient, documentation is required that clearly indicates the reason that the patient cannot use Herzuma, Trazimerz, Kanjinti, and Ogivri OR

C. Continuation of prior therapy within the past 365 days

| HCPSC codes | Description |
|---|---|
| Q5113 | Injection, Trastuzumab-pkrb, Biosimilar, (herzuma), 10 Mg |
| Q5116 | Injection, Trastuzumab-qyyp, Biosimilar, (trazimera), 10 Mg |
| Q5117 | Injection, Trastuzumab-anns, Biosimilar, (kanjinti), 10 Mg |
| Q5114 | Injection, Trastuzumab-dkst, Biosimilar, (ogivri), 10 Mg |
| J9355 | Injection, trastuzumab, excludes biosimilar, 10 mg |

F. Biphonsphonate (alendronate, ibandronate or risedronate, Prolia)

a. Applicable Drugs

vii. Preferred drug(s): alendronate, ibandronate or risedronate

viii. Non-preferred drug(s): Prolia (for Dx of osteoporosis with high risk of fractures.)

**Non-Preferred Product Step Therapy Criteria**

Prolia 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 alendronate, ibandronate or risedronate resulting in minimal clinical response to therapy with high risk fractures; and
2. Physician attests that in their clinical opinion the clinical response would be expected to be superior with Prolia than with alendronate, ibandronate or risedronate

OR

B. All of the following:

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

OR

C. Continuation of prior therapy within the past 365 day

| HCPSC codes | Description |
|---|---|
| No codes | alendronate, ibandronate or risedronate |
| J0897 | Prolia |

G. Oncology (Fulvestrant, Faslodex)

a. Applicable Drugs

i. Preferred drug(s): Fulvestrant

ii. Non-preferred drug(s): Faslodex

**Non-Preferred Product Step Therapy Criteria**

Faslodex 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 Fulvestrant 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 Faslodex than with Fulvestrant
   OR

B. All of the following:

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

OR

C. Continuation of prior therapy within the past 365 day

| HCPSC Code | Description |
|---|---|
| J9395 | Fulvestrant |
| J9395 | Faslodex |

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**Comment(s):**

1.0 Codes and descriptors listed in this document are provided for informational purposes only and may not be all inclusive or current. Listing of a code in this drug policy does not imply that the service described by the code is a covered or non-covered service. Benefit coverage for any service is determined by the member's policy of health coverage with the plan. Inclusion of a code in the table does not imply any right to reimbursement or guarantee claim payment. Other drug or medical policies may also apply.

2.0 **NOTE: The use of physician samples or manufacturer discounts does not guarantee later coverage under the provisions of the medical certificate and/or pharmacy benefit. All criteria must be met in order to obtain coverage of the listed drug product.**

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