



(formerly WellFirst Health)

Coverage of any drug intervention discussed in a Medica prior authorization guideline is subject to the limitations and exclusions outlined in the member's benefit certificate or policy and applicable state and/or federal laws.

- ☐ Commercial (Small & Large Group) ☐ ASO ☐ Exchange/ACA
☒ Medicare Advantage (MAPD)

Medicare Part B Step Therapy

MB2011

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 Health plan 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 Health plan 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. Bisphosphonate (alendronate, ibandronate or risedronate, Prolia, Evenity)

1. Applicable Drugs

Coverage of any drug intervention discussed in a Medica prior authorization guideline is subject to the limitations and exclusions outlined in the member's benefit certificate or policy and applicable state and/or federal laws.

- i. Preferred drug(s): alendronate, ibandronate or risedronate**
- ii. Non-preferred drug(s): Prolia, Evenity (for Dx of osteoporosis with high risk of fractures.)**

Non-Preferred Product Step Therapy Criteria

Prolia/Evenity 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 Prolia, 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
- 3. Physician attests that in their clinical opinion the clinical response would be expected to be superior with Evenity than with Prolia, 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 or Evenity; and
- 3. For patients, who are unable to tolerate Prolia, alendronate, ibandronate or risedronate or in the rare instance that Prolia, alendronate, ibandronate or risedronate is contraindicated for a patient, documentation is required that clearly indicates the reason that the patient cannot use Prolia, alendronate, ibandronate or risedronate .

OR

C. Continuation of prior therapy within the past 365 day

HCPCS codes	Description
No codes	alendronate, ibandronate or risedronate
J0897	Prolia
	Evenity

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B. Sick Cell (Hydroxyurea, Adaveko)**1. Applicable Drugs**

- i. Preferred drug(s): Hydroxyurea**
- ii. Non-preferred drug(s): Adakveo**

Non-Preferred Product Step Therapy Criteria

Adaveko 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 Hydroxyurea 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 Adakveo than with Hydroxyurea.

OR

B. All of the following:

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

OR

C. Continuation of prior therapy within the past 365 day

HCPSC Code	Description
N/a	Hydroxyurea
J0791	Adakveo

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C. Migraine (Emgality, Aimovig and Vyepti)

1. Applicable Drugs

- i. Preferred drug(s): Emgality and Aimovig**
- ii. Non-preferred drug(s): Vyepti**

Non-Preferred Product Step Therapy Criteria

Vyepti 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 Emgality or Aimovig 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 Vyepti than with Emgality or Aimovig.

OR

B. All of the following:

- 4. History of intolerance or adverse event to Aimovig or Emgality and
- 5. Physician attests that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Vyepti; and
- 6. For patients, who are unable to tolerate Aimovig and Emgality or in the rare instance that Aimovig or Emgality are contraindicated for a patient, documentation is required that clearly indicates the reason that the patient cannot use Aimovig or Emgality .

OR

C. Continuation of prior therapy within the past 365 day

HCPCS Code	Description
J8499	Aimovig
J8499	Emgality
J3032	Vyepti

Coverage of any drug intervention discussed in a Medica prior authorization guideline is subject to the limitations and exclusions outlined in the member's benefit certificate or policy and applicable state and/or federal laws.

D. Systemic Lupus Disease (Oral or injectable Hydroxychloroquine, methotrexate, azathioprine, mycophenolate)

1. Applicable Drugs

- i. Preferred drug(s): Oral or injectable Hydroxychloroquine, methotrexate, azathioprine, mycophenolate**
- ii. Non-preferred drug(s): Benlysta or Saphnelo**

Non-Preferred Product Step Therapy Criteria

Benlysta or Saphnelo 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 with (1) of the following (IV or Oral) :
 - i. Oral: Hydroxychloroquine, methotrexate, azathioprine, mycophenolate OR
 - ii. Intravenous: Hydroxychloroquine, methotrexate, azathioprine, mycophenolate
- 2. Physician attests that in their clinical opinion the clinical response would be expected to be superior with Benlysta or Saphnelo than with preferred products.

OR

B. All of the following:

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

OR

C. Continuation of prior therapy within the past 365 day

HCPCS Code	Description
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Coverage of any drug intervention discussed in a Medica prior authorization guideline is subject to the limitations and exclusions outlined in the member's benefit certificate or policy and applicable state and/or federal laws.

N/A	Hydroxychloroquine
N/A	Methotrexate
N/A	Azathiopurine
N/A	Mycophenolate
J0490	Benlysta
J3590	Saphnelo

E. Gout treatment (Allopurinol, Febuxostat, Krystexxa)

1. Applicable Drugs

- i. Preferred drug(s): Allopurinol, Febuxostat**
- ii. Non-preferred drug(s): Krystexxa**

Non-Preferred Product Step Therapy Criteria

Krystexxa may be used when all of the criteria listed under (1) ONE of the following sections A., B., or C. are satisfied:

A. All of the following:

- 1. History of use with Allopurinol or Febuxostat
- 2. Physician attests that in their clinical opinion the clinical response would be expected to be superior with Krystexxa than with preferred products.

OR

B. All of the following:

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

OR

C. Continuation of prior therapy within the past 365 day

HCPCS Code	Description
n/a	Allopurinol

Coverage of any drug intervention discussed in a Medica prior authorization guideline is subject to the limitations and exclusions outlined in the member's benefit certificate or policy and applicable state and/or federal laws.

n/a	Febuxostat
J2507	Krystexxa

F. Crohns Disease (Tysabri, Entyvio)

1. Applicable Drugs

- i. **Preferred drug(s):** Formulary self-injectable TNF- α inhibitors (e.g. HUMIRA); Formulary medical benefit infusables an infliximab product
- i. **Non-preferred drug(s): Tysabri, Entyvio**

Non-Preferred Product Step Therapy Criteria

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

A. For Tysabri and Entyvio the following:

1. History of use with 1 of the following Prior to Tysabri and Entyvio : self-injectable TNF- α inhibitors (e.g. HUMIRA); Formulary medical benefit infusables, infliximab.
1. Physician attests that in their clinical opinion the clinical response would be expected to be superior with Tysabri or Entyvio than with preferred products because member has an aggressive disease

OR

B. All of the following:

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

OR

C. Continuation of prior therapy within the past 365 day

Description	HCPCS Code
Tysabri	J2323

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Entyvio	J3380
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G. Rheumatoid Arthritis:

1. Applicable Drugs

i. Preferred drugs: Humira or biosimilar (adalimumab), Enbrel, infliximab, and Rinvoq

ii. Non-preferred drug(s) IV or Subcutaneous: Orencia, Actemra or Simponi Aria, Humira (adalimumab), Enbrel

Non-Preferred Product Step Therapy Criteria

Orencia, Actemra or Simponi 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 with (2) of the following therapies :
 - i. Enbrel, Humira, Rinvoq or infliximab
2. Physician attests that in their clinical opinion the clinical response would be expected to be superior with Orencia, Actemra or Simponi than with preferred products.

OR

B. All of the following:

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

OR

C. Continuation of prior therapy within the past 365 day

HCPCS Code	Description
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N/A	Rinvoq
J0135	Humira
J1438	Enbrel
J0490	infliximab
J0129	Orencia
J3358	Stelara
J3262	Actemra

H. Polyarticular juvenile idiopathic arthritis (PJIA):

1. Applicable Drugs

i. Preferred drugs(Enbrel (etanercept), Humira (adalimumab),Inj Methotrexate

ii. Non-preferred drug(s) IV or Subcutaneous: Orencia, Actemra

Non-Preferred Product Step Therapy Criteria

Orencia, Actemra 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 with (2) of the following therapies :
 - i. Enbrel, Humira,injectable Methotrexate
2. Physician attests that in their clinical opinion the clinical response would be expected to be superior with Orencia, Actemra than with preferred products.

OR

B. All of the following:

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

OR

C. Continuation of prior therapy within the past 365 day

HCPCS Code	Description
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N/A	Injectable Methotrexate
J0135	Humira
J1438	Enbrel
J0129	Orencia
J3262	Actemra

I. Psoriatic arthritis:

1. Applicable Drugs

i. Preferred drugs(Enbrel (etanercept), Humira (adalimumab), Otezla, Cosentyx, Taltz, Stelara

ii. Non-preferred drug(s) IV or Subcutaneous: Orencia, Simponi Aria

Non-Preferred Product Step Therapy Criteria

Orencia, Simponi 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 with (2) of the following therapies :
 - i. Enbrel, Humira, Cosentyx, Taltz, Stelara
2. Physician attests that in their clinical opinion the clinical response would be expected to be superior with Orencia, Simponi than with preferred products.

OR

B. All of the following:

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

OR

C. Continuation of prior therapy within the past 365 day

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HCPCS Code	Description
J1602	Simponi Aria
J0135	Humira
J1438	Enbrel
J0129	Orencia
N/a	Cosentyx
N/a	Taltz
J3358	Stelara

J. Ankylosing spondylitis:

1. Applicable Drugs

i. Preferred drugs(Enbrel (etanercept), Humira (adalimumab) Cosentyx

ii. Non-preferred drug(s) IV or Subcutaneous: Simponi Aria

Non-Preferred Product Step Therapy Criteria

Simponi 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 with (2) of the following therapies :
 - i. Enbrel, Humira, Cosentyx,
2. Physician attests that in their clinical opinion the clinical response would be expected to be superior with Simponi, than with preferred products.

OR

B. All of the following:

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

OR

C. Continuation of prior therapy within the past 365 day

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HCPCS Code	Description
J1602	Simponi Aria
J0135	adalimumab
J1438	Entercept
n/a	Cosentyx

K. Asthma

1. Applicable Drugs

- i. Preferred drug(s): Oral : Systemic Oral corticosteroid, medium or High dose inhaled corticosteroid (ICS) in combination with long-acting beta agonist (LABA), leukotriene receptor antagonist, tiotropium; systemic Injectable: corticosteroids**
- ii. Non-preferred drug(s): Xolair, Cinqair**

Non-Preferred Product Step Therapy Criteria

Xolair or Cinqair 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 with (1) of the following (IV or Oral) therapies :
 - i. Systemic Oral corticosteroid, medium or High dose inhaled corticosteroid (ICS) in combination with long-acting beta agonist (LABA), leukotriene receptor antagonist, tiotropium; systemic Injectable: corticosteroids
2. Physician attests that in their clinical opinion the clinical response would be expected to be superior with Xolair, Cinqair, than with preferred products.

OR

B. All of the following:

1. History of intolerance or adverse event to Preferred product and
2. Physician attests that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Xolair, Cinqair; and

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3. For patients, who are unable to tolerate Preferred products or in the rare instance that preferred products are contraindicated for a patient, documentation is required that clearly indicates the reason that the patient cannot use any of the preferred products .

OR

- C. Continuation of prior therapy within the past 365 day

HCP/CS Code	Description
N/A	Oral steroids/IV steroids
N/A	Medium or high dose inhaled corticosteroid
N/A	Long acting beta agonis
N/A	Leukotriene receptor
J2357	Xolair
J2786	Cinqair

L. Chronic idiopathic Urticaria

1. Applicable Drugs

i. Preferred drug(s): Injectable or oral H1 antihistamines

ii. Non-preferred drug(s): Xolair,

Non-Preferred Product Step Therapy Criteria

Xolair 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 with (1) of the following (IV or Oral) therapies :
 - i. Oral or injectable antihistamines
2. Physician attests that in their clinical opinion the clinical response would be expected to be superior with Xolair than with preferred products.

OR

B. All of the following:

1. History of intolerance or adverse event to Preferred product and
2. Physician attests that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Xolair, and

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3. For patients, who are unable to tolerate Preferred products or in the rare instance that preferred products are contraindicated for a patient, documentation is required that clearly indicates the reason that the patient cannot use any of the preferred products .

OR

C. Continuation of prior therapy within the past 365 day

HCPCS Code	Description
N/A	Oral / IV antihistamines
J2357	Xolair

M. Treatment-resistant Depression

1. Applicable Drugs

i. Preferred drug: Oral Antidepressants

ii. Non-preferred drug(s): Spravato

Non-Preferred Product Step Therapy Criteria

Spravato 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 with (1) of the following therapies :
 - i. Oral antidepressants
2. Physician attests that in their clinical opinion the clinical response would be expected to be superior with Spravato than with preferred products.

OR

B. All of the following:

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

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OR

C. Continuation of prior therapy within the past 365 day

HCPCS Code	Description
N/A	Oral Antidepressants
S0013	Spravato

N. Iron Replacement

1. Applicable Drugs

i. Preferred drug: Venofer/Infed/Ferrecit/Fereheme

ii. Non-preferred drug(s): Triferic/Injectafer/Monoferric/Triferic AVNU

Non-Preferred Product Step Therapy Criteria

Triferic/Injectafer/Monoferric/Triferic AVNU may be used when all of the criteria listed under ONE of the following sections A., B., or C. are satisfied:

D. All of the following:

1. History of use with (1) of the following therapies :
 - i. Venofer/Infed/Ferrecit/fereheme
2. Physician attests that in their clinical opinion the clinical response would be expected to be superior with Triferic/Injectafer/Monoferric/Triferic AVNU than with preferred products.

OR

E. All of the following:

4. History of intolerance or adverse event to Preferred product and
5. Physician attests that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Triferic/Injectafer/Monoferric/Triferic AVNU ; and

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6. For patients, who are unable to tolerate Preferred products or in the rare instance that preferred products are contraindicated for a patient, documentation is required that clearly indicates the reason that the patient cannot use any of the preferred products .

OR

- F. Continuation of prior therapy within the past 365 day

HCPCS Code	Description
J1758	Venofer
J2750	Infed
J2917	Ferrecit
Q0138	Fereheme
J1446/J1444	Triferic
J1439	Injectafer
J1437	Monoferic
J1445	Triferic AVNU

O. Skeletal related events with Multiple Myeloma and Prevention of hypercalcemia of malignancy

1. Applicable Drugs

- i. Preferred drug(s): Reclast (Zolendronic acid)
- ii. Non-preferred drug(s): Xgeva

Non-Preferred Product Step Therapy Criteria

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

D. All of the following:

1. History of use of Reclast 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 Xgeva than with Reclast
- 3.

OR

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E. All of the following:

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

OR

F. Continuation of prior therapy within the past 365 day

HCP codes	Description
J3489	Reclast
J0897	Xgeva

P. Erythropoietic Agents (Procrit, Retacrit)

1. 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

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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.

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

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

1. Applicable Drugs

- i. **Preferred drug(s): Avsola**
- ii. **Non-preferred drug(s): Remicade, Renflexis, Inflectra**

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 Avsola 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, Renflexis or Inflectra than with Avsola.

OR

B. All of the following:

1. History of intolerance or adverse event to Avsola;
2. Physician attests that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Remicade, Renflexis and Inflectra, and

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3. For patients, who are unable to tolerate Avsola 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.

HCPSC Code	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

R. Colony Stimulating Factors Short-Acting (Granix, Neupogen, Nivestym, Zarxio)

1. Applicable Drugs

- i. **Preferred drug(s): Zarxio, Nivestym**
- ii. **Non-preferred drug(s): Granix, Neupogen, Leukine**

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

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

HCPSC 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

S. Colony Stimulating Factors Long-Acting (Neulasta, Udenyca, Fulphila, Ziextenzo Rolvedron, Ryzneuta)

a. Applicable Drugs

- i. Preferred drug(s): , Fulphila, Nyprevia
- ii. Non-preferred drug(s): Neulasta, Udenyca, Ziextenzo, Rolvedron, Ryzneuta

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 Fulphila or Nyprevia 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 Rolvedrom, Ryzneuta, Neulasta, Ziextenzo and Udenyca than with, Fulphila or Nyprevia
- OR

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

OR

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

HCPSC Code	Description
Medicare Step B Therapy	20 of 29

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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 Q5120
Q5120	Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo) 0.5mg
J1449 / J9361	Injection, Rolvedron 0.1mg J1449 / J9361 Ryzneuta 0.5mg

*Preferred Drug(s)/Product(s)

T. EGFR inhibitors (Avastin, Mvasi, Zirabev)

1. Applicable Drugs

i. Preferred drug(s): Zirabev

ii. Non-preferred drug(s): Avastin, Mvasi

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:

- History of use of Zirabev resulting in minimal clinical response to therapy; and
- Physician attests that in their clinical opinion the clinical response would be expected to be superior with than with Avastin and Mvasi.

OR

B. All of the following:

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

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Q5189	Injection, bevacizumab-bvzr, biosimilar, (zirabev), 10 mg
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U. CD-20 Directed antibody (Rituxan, Truxima, and Ruxience)

1. Applicable Drugs

- i. Preferred drug(s): Truxima and Ruxience**
- ii. Non-preferred drug(s): Rituxan / Rituxan Hycela**

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/Rituxan Hycela ; 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

HCPCS	Description
Q5115	Injection, rituximab-abbs, biosimilar, (truxima), 10 mg
Q5119	Injection, rituximab-pvvr, biosimilar, (ruxience), 10 mg
J9312	Rituxan
J9311	Rituxan Hycela

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

1. Applicable Drugs

- i. Preferred drug(s): Herzuma, Trazimerz
- ii. Non-preferred drug(s): Herceptin, Kanjinti, Ogivri

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

OR

B. All of the following:

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

C. Continuation of prior therapy within the past 365 days

HCPCS 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

W. Cholesterol (Injectable Repatha or Praluent)

1. Applicable Drugs

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ii. Preferred drug(s): Repatha Or Praulent

iii. Non-preferred drug(s): Eveeka

Non-Preferred Product Step Therapy Criteria

Eveeka 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 with 1 of the following : Repatha or Praulent
2. Physician attests that in their clinical opinion the clinical response would be expected to be superior with Eveeka than with preferred products.

OR

B. All of the following:

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

OR

C. Continuation of prior therapy within the past 365 day

D.

X. Hypercholestermia (Lipitor, Crestor, Leqvio)

1. Applicable Drugs

iii. Preferred drug(s): Lipitor or Crestor

iv. Non-preferred drug(s): Leqvio

Non-Preferred Product Step Therapy Criteria

Leqvio 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 to Unable to meet LDL goal + heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease

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(ASCVD with lipitor or Crestor 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 Leqvio

OR

B. All of the following:

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

C. Continuation of prior therapy within the past 365 days

HCPCS codes	Description
n/a	Lipitor
n/a	Crestor
J3490	Leqvio

Y. VEGF (Intraocular vascular endothelial growth factor inhibitor class)

1. Applicable Drugs

- i. **Preferred drug(s): Bevacizumab**
- ii. **Non-preferred drug(s):** Byooviz, Cimerli, Lucentis (ranibizumab), Eylea, Eylea HD, Vabysmo

Non-Preferred Product Step Therapy Criteria

Orencia 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 with 3 doses of the following : Bevacizumab
2. Physician attests that in their clinical opinion the clinical response would be expected to be superior with Byooviz, Cimerli, Lucentis (ranibizumab), Eylea, Eylea HD, Vabysmo than with preferred products.

OR

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B. All of the following:

3. History of intolerance or adverse event to Preferred product and
4. Physician attests that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Byooviz, Cimerli, Lucentis (ranibizumab), Eylea, Eylea HD, Vabysmo and
5. For patients, who are unable to tolerate Preferred products or in the rare instance that preferred products are contraindicated for a patient, documentation is required that clearly indicates the reason that the patient cannot use any of the preferred products .

OR

Continuation of prior therapy within the past 365 day

HCPSCS codes	Description
Q5124	Byooviz
Q5128	Cimerli
J2778	Lucentis (ranibizumab)
J0178	Eylea
J0177	Eylea HD
J2777	Vabysmo

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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	Committee/Source	Date(s)
Document Created:	Medical Policy Committee/Health Services Division/Pharmacy Services	October 21, 2020
Revised:	Medical Policy Committee/Health Services Division/Pharmacy Services	October 20, 2021
	Medical Policy Committee/Health Services Division/Pharmacy Services	April 20, 2022
	Medical Policy Committee/Health Services Division/Pharmacy Services	October 19, 2022
	Medical Policy Committee/Health Services Division/Pharmacy Services	March 15, 2023
	Medical Policy Committee/Health Services Division/Pharmacy Services	December 2023
Reviewed:	Medical Policy Committee/Health Services Division/Pharmacy Services	October 20, 2021
	Medical Policy Committee/Health Services Division/Pharmacy Services	April 20, 2022
	Medical Policy Committee/Health Services Division/Pharmacy Services	October 19, 2022
	Medical Policy Committee/Health Services Division/Pharmacy Services	March 15, 2023
	Medical Policy Committee/Health Services Division/Pharmacy Services	December 2023
	Medical Policy Committee/Health Services Division/Pharmacy Services	January 17, 2024
	Medical Policy Committee/Health Services Division/Pharmacy Services	May 15, 2024

Published: 06/01/2024

Effective: 06/01/2024

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https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761054orig1s000lbl.pdf 3.
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