Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Medicare Part B Step Therapy		
MNG #: 040	☒**SCO** ☒**One Care**	**Prior Authorization Needed?** ☒**Yes** ☐**No**
Clinical: ☒	**Operational:** ☐	**Informational:** ☐
Medicare Benefit: ☒**Yes** ☐**No**	**Approval Date:** 08/05/2020	**Effective Date:** 12/18/2020
Last Revised Date: 10/13/2020	**Next Annual Review Date:** 10/13/2021	**Retire Date:**

OVERVIEW:

This CCA Medical Benefit Injectable Policy is for informational purposes only and does not constitute or replace medical advice. Physicians, hospitals and other providers are expected to care for their patients in such a way that they can use or administer drugs/biologicals in the most effective and clinically appropriate manner. 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). If there is a discrepancy between this policy and the member's EOC, the member's EOC provision(s) will govern.

In the event of a conflict between this policy and Medicare National Coverage Determinations (NCD) or Local Coverage Determinations (LCD); the Medicare NCD/LCD will be applied.

Each class of medical benefit injectables covered under Medicare Part B referenced below includes preferred drugs(s)/product(s). Step therapy 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 along with additional criteria. If a provider administers a non-preferred drug/product without obtaining prior authorization, CCA may deny the claims for the non-preferred drug. The medical benefit injectables that include non- preferred drug(s)/product(s) subject to prior authorization, and preferred drug(s)/product(s), can be found below.

This Medical Benefit Injectable Policy is applicable to Commonwealth Care Alliance's (CCA) One Care (Medicare-Medicaid) plan **AND** Senior Care Options (SCO) duals plan.
Experimental and investigational procedures, items, and medications are not covered. For coverage requirements, refer to the Experimental and Investigational Drug MNG.

DECISION GUIDELINES:

This CCA policy supplements Medicare Part B NCD, LCD, and regulatory manuals for determining coverage under Medicare Part B medical benefits. This policy implements a prior authorization or Step Therapy requirement for prescriptions or administrations of medical benefit injectables only.

- A member cannot and will not be required under this policy to change a current drug/product.

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- For the purposes of this policy, a current drug/product means the member has a paid claim or clear clinical documentation (non-sample) for the drug/product within the past 365 days (claims look-back period).

DESCRIPTION OF SERVICES:
Specific classes of medical benefit injectables covered under Medicare Part B will include non-preferred therapies that 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. If a provider administers a non-preferred therapy without obtaining prior authorization, CCA may deny the claim for the non-preferred therapy. Prior authorization requirements for preferred biologic therapies can be found at Select Biologic Agents MNG..

MEDICAL THERAPEUTIC DRUG CLASSES
There are specific classes of medical benefit injectables covered under Medicare Part B that will include preferred and non-preferred drugs or products. The drugs or products are for biosimilars drugs.

There are an increasing number of FDA approved biosimilar drugs/products available in marketplace. A biosimilar is a biological product approved based on data demonstrating that it is highly similar to a FDA- approved biological product, known as the reference product, and that there are no clinically significant differences between the biosimilar product and the reference product. Biosimilars are at as least likely to produce equivalent therapeutic results and are lower cost than brand name alternatives.

This policy applies step therapy for the following drugs:

Drug Name
Bevacizumab
Filgrastim
Infliximab
Pegfilgrastim
Rituximab
Trastuzumab

Preferred Drug List: https://www.commonwealthcarealliance.org/getmedia/910264cd-01e4-4002-aafb-fad8e3992336/Medicare-Part-B-Step-Therapy-Preferred-Drug-List-attachment

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STEP THERAPY (NEW STARTS ONLY) DRUG CRITERIA

BEVACIZUMAB

PREFERRED DRUG(S): Mvasi (bevacizumab-awwb) or Zirabev (bevacizumab-bvzr)

- Non-preferred drug(s): Avastin® (bevacizumab)
- Non-preferred step therapy criteria:
    - Avastin® (bevacizumab) may be used when the criteria listed under one of the following Sections I, II, III are satisfied:

I. All of the following:
- **A.** History of use of Mvasi (bevacizumab-awwb) or Zirabev (bevacizumab-bvzr) resulting in minimal clinical response **AND**
- B. Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Avastin® (bevacizumab)

OR

II. All of the following:
- **A.** History of intolerance or adverse event to Mvasi (bevacizumab-awwb) or Zirabev (bevacizumab-bvzr) **AND**
- **B.** Physician attestation that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Avastin® (bevacizumab) **AND**
- C. For members who are unable to tolerate Mvasi (bevacizumab-awwb) or Zirabev (bevacizumab-bvzr) or in the rare instance that it is contraindicated for a member, documentation is required and must indicate the reason why the member cannot use Mvasi (bevacizumab-awwb) or Zirabev (bevacizumab-bvzr).

OR

III. Use of requested non-preferred drug(s) within the past 365 days.

Code	Description *(mg = milligram)
J9035	Injection, Avastin® (bevacizumab), 10mg
Q5107	Injection, Mvasi (bevacizumab-awwb) 10mg
Q5118	Injection, Zirabev (bevacizumab-bvzr) 10mg

INFLIXIMAB

PREFERRED DRUG(S): Renflexis (infliximab-abda) or Inflectra (infliximab-dyyb), Avsola (infliximab-axxq)

- Non-preferred drug(s): Remicade® (infliximab)
- Non-preferred step therapy criteria:

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- Remicade® (infliximab)may be used when the criteria listed under one of the following sections I, II, III are satisfied:

I. All of the following:

A. Trial of at least 14 weeks of Renflexis (infliximab-abda), Inflectra (infliximab-dyyb) or Avsola (infliximab-axxq) resulting in minimal clinical response to therapy and residual disease activity **AND**

B. Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Remicade® (infliximab)rather than with Renflexis (infliximab-abda) or Inflectra (infliximab-dyyb) or Avsola (infliximab-axxq)

OR

II. All of the following:

A. History of intolerance or adverse event to Renflexis (infliximab-abda) or Inflectra (infliximab-dyyb) or Avsola (infliximab-axxq); **AND**

B. Physician attestation that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Remicade® (infliximab)**AND**

C. For members who are unable to tolerate Renflexis (infliximab-abda) or Inflectra (infliximab-dyyb) or Avsola (infliximab-axxq) or in the instance that the preferred products above are contraindicated for a member, documentation is required and must indicate the reason why the member cannot take one of the above preferred products. The rationale must be clearly documented.

OR

III. Use of requested non-preferred drug(s) within the past 365 days.

HCPCS CODES:

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

FILGRASTIM: SHORT-ACTING

PREFERRED DRUG(S): Nivestym (filgrastim-aafi), Zarixo (filgrastim-sndz)

- Non-preferred drug(s): Granix (filgrastim-tbo), Neupogen® (filgrastim)
- Non-preferred step therapy criteria: Granix (filgrastim-tbo), Neupogen® (filgrastim) may be used when the criteria listed under one of the following Sections I, II, and III are satisfied:

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I. Both of the following:
   - **A.** History of use of resulting in minimal clinical response to therapy **AND**
   - B. Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Neupogen or Granix

OR

II. All of the following:
   - A. History of Nivestym (filgrastim-aafi), Zarixo (filgrastim-sndz) intolerance or adverse event to Nivestym (filgrastim-aafi) or Zarixo (filgrastim-sndz)
   - B. Physician attestation that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Granix (filgrastim-tbo), Neupogen® (filgrastim)
   - C. For members who are unable to tolerate Nivestym (filgrastim-aafi) or Zarixo (filgrastim-sndz) or in the rare instance that Nivestym (filgrastim-aafi) or Zarixo (filgrastim-sndz) is contraindicated for a member, documentation is required and must clearly indicate the reason why the member cannot use Nivestym (filgrastim-aafi) or Zarixo (filgrastim-sndz)

OR

III. Use of requested non-preferred drug(s) within the past 365 days.

HCPCS CODES

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

PEGFILGRASTIM: LONG ACTING

PREFFERRED DRUGS: Fulphilia (pegfilgrastim-jmdb)

- Non-preferred drug(s): Neulasta® (pegfilgrastim), Udenyca (pegfilgrastim-cbqv), Ziextenzo (pegfilgrastim-bmez)
- Non-preferred step therapy criteria: Neulasta® (pegfilgrastim), Udenyca (pegfilgrastim-cbqv), Ziextenzo (pegfilgrastim-bmez) may be used when the criteria listed under one of the following Sections I, II, III are

satisfied:

I. All of the following:
A. History of use of Fulphilia (pegfilgrastim-jmdb) resulting in minimal clinical response **AND**

B. Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Neulasta® (pegfilgrastim), Udenyca (pegfilgrastim-cbqv), Ziextenzo (pegfilgrastim-bmez)

OR

II. All the following:
A. History of intolerance or adverse event to Fulphilia (pegfilgrastim-jmdb) **AND**
B. Physician attestation that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Neulasta® (pegfilgrastim), Udenyca (pegfilgrastim-cbqv), Ziextenzo (pegfilgrastim-bmez) **AND**
C. For members who are unable to tolerate Fulphilia (pegfilgrastim-jmdb) or in the rare instance that Fulfilia is contraindicated for a member, documentation is required and must clearly indicate the reason why the member cannot use Fulphilia (pegfilgrastim-jmdb)

OR

III. Use of requested non-preferred drug(s) within the past 365 days.

HCPCS CODES

Code	Description *(mg = milligram)
J2505	Injection, pegfilgrastim, (Neulasta) 6 mg
Q5108	Injection, pegfilgrastim-jmdb, (Fulphila), 0.5 mg
Q5111	Injection, pegfilgrastim-cbqv, (Udenyca), 0.5 mg
Q5120	Injection, pegfilgrastim-bmez, (Ziextenzo) 0.5mg

TRASTUZUMAB

PREFERRED DRUG: Ogivri (trastuzumab-dkst)

- Non-Preferred Drugs: Herceptin® (trastuzumab), Herzuma (trastuzumab-pkrb), Kanjinti (trastuzumab-anns), Ontruzant (trastuzumab-dttb), and Trazimera (rastuzumab-qyyp)

- Non-Preferred Step Therapy criteria for: Herceptin® (trastuzumab), Herzuma (trastuzumab-pkrb), Kanjinti (trastuzumab-anns), Ontruzant (trastuzumab-dttb), Trazimera (rastuzumab-qyyp) may be used when the

criteria listed under one of the following Sections I, II, III are satisfied:

OR

I. All of the following:

A. History of use of Ogivri (trastuzumab-dkst) resulting in minimal clinical response **AND**
B. Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Herceptin® (trastuzumab), Herzuma (trastuzumab-pkrb), Kanjinti (trastuzumab-anns), Ontruzant (trastuzumab-dttb), and Trazimera (rastuzumab-qyyp)

OR

II. All of the following:
A. History of intolerance or adverse event to Ogivri (trastuzumab-dkst) **AND**
B. Physician attestation that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Herceptin® (trastuzumab), Herzuma (trastuzumab-pkrb), Kanjinti (trastuzumab-anns), Ontruzant (trastuzumab-dttb), and Trazimera (rastuzumab-qyyp) **AND**
C. For members who are unable to tolerate Ogivri (trastuzumab-dkst) or in the rare instance that Ogivri (trastuzumab-dkst) is contraindicated for a member, documentation is required and must clearly indicate the reason why the member cannot use Ogivri (trastuzumab-dkst)

OR

III. Use of requested non-preferred drug(s) within the past 365 days.

HCPCS CODES

Code	Description *(mg = milligrams)
J9355	Injection, Herceptin® (trastuzumab),10mg
Q5112	Injection, Ontruzant (trastuzumab-dttb), 10mg
Q5113	Injection, Herzuma (trastuzumab-pkrb), 10mg
Q5114	Injection, Ogivri (trastuzumab-dkst), 10mg
Q5116	Injection, Trazimera (rastuzumab-qyyp), 10mg
Q5117	Injection, Kanjinti (trastuzumab-anns), 10mg

RITUXIMAB

PREFERRED DRUG: Truxima (rituximab-abbs)

- Non-Preferred Drugs: Rituxan®(rituximab) and Ruxience (rituximab-pvvr)
- Non-Preferred Step Therapy criteria for: Rituxan®(rituximab) and Ruxience (rituximab-pvvr) may be used when the criteria listed under one of the following sections I, II, III are satisfied:

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I. All of the following:
- **A.** History of use of Truxima (rituximab-abbs) resulting in minimal clinical response **AND**
- B. Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Rituxan®(rituximab) and Ruxience (rituximab-pvvr)

OR

II. All of the following:
- **A.** History of intolerance or adverse event to Truxima (rituximab-abbs) **AND**
- **B.** Physician attestation that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Rituxan®(rituximab) and Ruxience (rituximab-pvvr) **AND**
- C. For members who are unable to tolerate Truxima (rituximab-abbs) or in the rare instance that Truxima (rituximab-abbs) is contraindicated for a member, documentation is required and must clearly indicate the reason why the member cannot use Truxima (rituximab-abbs)

OR

III. Use of requested non-preferred drug(s) within the past 365 days.

HCPCS CODES

Code	Description *(mg = milligrams)
J9312	Injection, Rituxan (rituximab), 10mg
Q5115	Injection, Truxima (rituximab-abbs) 10mg
Q5119	Injection, Ruxience (rituximab-pvvr) 10mg

LIMITATIONS/EXCLUSIONS:

Senior Care Options (Massachusetts Health Only-MHO) members.

Disclaimer:

This Medical Necessity Guideline is not a rigid rule. As with all of CCA's criteria, the fact that a member does not meet these criteria does not, in and of itself, indicate that no coverage can be issued for these services. Providers are advised, however, that if they request services for any member who they know does not meet our criteria, the request should be accompanied by clear and convincing documentation of medical necessity. The preferred type of documentation is the letter of medical necessity, indicating that a request should be covered either because there is supporting science indicating medical necessity (supporting literature (full text preferred) should be attached to the request), or describing the member's unique clinical circumstances, and describing why this service or supply will be more effective and/or less costly than another service which would otherwise be covered. Note that both supporting scientific evidence and a description of the member's unique clinical circumstances will generally be required.

RELATED REFERENCES:

1. https://www.cms.gov/Medicare/HealthPlans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo

_8_7_2018.pdf
2. 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
3. https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-prior-authorization-and-step-therapy-part-b-drugs
4. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update
5. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS
6. https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars

ATTACHMENTS:

EXHIBIT A: Part B Step Therapy Preferred Drug List	**To be linked once MNG approved**
EXHIBIT B	

REVISION LOG:

REVISION DATE	DESCRIPTION

APPROVALS:

Derek McFerran	Director, Pharmacy Program
CCA Senior Clinical Lead [Print]	**Title [Print]**
Derek McFerran	08/05/2020
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CCA Senior Operational Lead [Print]	**Title [Print]**
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Lori Tishler	Sr. Vice President, Medical Services
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Lori Tishler	08/05/2020
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