Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Medicare Part B Step Therapy

<table>
<thead>
<tr>
<th>MNG #: 040</th>
<th>SCO</th>
<th>One Care</th>
<th>Prior Authorization Needed?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☒</td>
<td>☒</td>
<td>☒</td>
<td>☒ Yes ☐ No</td>
</tr>
</tbody>
</table>

| Clinical: ☒ | Operational: ☐ | Informational: ☐ |
| Medicare Benefit: ☒ | 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 least likely to produce equivalent therapeutic results and are lower cost than brand name alternatives.

This policy applies step therapy for the following drugs:

<table>
<thead>
<tr>
<th>Drug Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bevacizumab</td>
</tr>
<tr>
<td>Filgrastim</td>
</tr>
<tr>
<td>Infliximab</td>
</tr>
<tr>
<td>Pegfilgrastim</td>
</tr>
<tr>
<td>Rituximab</td>
</tr>
<tr>
<td>Trastuzumab</td>
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</tbody>
</table>

Medicare Part B Step Therapy Preferred Drug List

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:
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- 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.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description *(mg = milligram)</th>
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</thead>
<tbody>
<tr>
<td>J9035</td>
<td>Injection, Avastin® (bevacizumab), 10mg</td>
</tr>
<tr>
<td>Q5107</td>
<td>Injection, Mvasi (bevacizumab-awwb) 10mg</td>
</tr>
<tr>
<td>Q5118</td>
<td>Injection, Zirabev (bevacizumab-bvzr) 10mg</td>
</tr>
</tbody>
</table>

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:
  - 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
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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:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description *(mg = milligram)</th>
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<tbody>
<tr>
<td>J1745</td>
<td>Injection, infliximab (Remicade®), 10mg</td>
</tr>
<tr>
<td>Q5103</td>
<td>Injection, infliximab-dyyb, biosimilar (Inflectra), 10mg</td>
</tr>
<tr>
<td>Q5104</td>
<td>Injection, infliximab-abda, biosimilar (Renflexis), 10mg</td>
</tr>
<tr>
<td>Q5121</td>
<td>Injection, infliximab-axxq, biosimilar (Avsola), 10mg</td>
</tr>
</tbody>
</table>

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:

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
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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

<table>
<thead>
<tr>
<th>Code</th>
<th>Description (*mcg = microgram)</th>
</tr>
</thead>
<tbody>
<tr>
<td>J1442</td>
<td>Injection, filgrastim (G-CSF), (Neupogen) 1 mcg</td>
</tr>
<tr>
<td>J1447</td>
<td>Injection, filgrastim-tbo, (Granix)1 mcg</td>
</tr>
<tr>
<td>Q5101</td>
<td>Injection, filgrastim-sndz, (Zarxio) 1 mcg</td>
</tr>
<tr>
<td>Q5110</td>
<td>Injection, filgrastim-aafi, (Nivestym), 1 mcg</td>
</tr>
</tbody>
</table>

PEGFILGRASTIM: LONG ACTING

PREFERRED 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
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B. Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Neulasta® (pegfilgrastim), Udenyca (pegfilgrastim-cbqv), Ziextenso (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), Ziextenso (pegfilgrastim-bmez) AND
   C. For members who are unable to tolerate Fulphilia (pegfilgrastim-jmdb) or in the rare instance that Fulphilia 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

<table>
<thead>
<tr>
<th>Code</th>
<th>Description *(mg = milligram)</th>
</tr>
</thead>
<tbody>
<tr>
<td>J2505</td>
<td>Injection, pegfilgrastim, (Neulasta) 6 mg</td>
</tr>
<tr>
<td>Q5108</td>
<td>Injection, pegfilgrastim-jmdb, (Fulphila), 0.5 mg</td>
</tr>
<tr>
<td>Q5111</td>
<td>Injection, pegfilgrastim-cbqv, (Udenyca), 0.5 mg</td>
</tr>
<tr>
<td>Q5120</td>
<td>Injection, pegfilgrastim-bmez, (Ziextenso) 0.5mg</td>
</tr>
</tbody>
</table>

TRASTUZUMAB

PREFERRED DRUG: Ogivri (trastuzumab-dkst)

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

- Non-Preferred Step Therapy criteria for: Herceptin® (trastuzumab), Herzuma (trastuzumab-pkrb), Kanjinti (trastuzumab-anns), Ontruzant (trastuzumab-dttb), Trazimera (trastuzumab-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:
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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.

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<th>Code</th>
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<tbody>
<tr>
<td>J9355</td>
<td>Injection, Herceptin® (trastuzumab), 10mg</td>
</tr>
<tr>
<td>Q5112</td>
<td>Injection, Ontruzant (trastuzumab-dttb), 10mg</td>
</tr>
<tr>
<td>Q5113</td>
<td>Injection, Herzuma (trastuzumab-pkrb), 10mg</td>
</tr>
<tr>
<td>Q5114</td>
<td>Injection, Ogivri (trastuzumab-dkst), 10mg</td>
</tr>
<tr>
<td>Q5116</td>
<td>Injection, Trazimera (rastuzumab-qyyp), 10mg</td>
</tr>
<tr>
<td>Q5117</td>
<td>Injection, Kanjinti (trastuzumab-anns), 10mg</td>
</tr>
</tbody>
</table>

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:

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)
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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.

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<table>
<thead>
<tr>
<th>Code</th>
<th>Description *(mg = milligrams)</th>
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<tbody>
<tr>
<td>J9312</td>
<td>Injection, Rituxan (rituximab), 10mg</td>
</tr>
<tr>
<td>Q5115</td>
<td>Injection, Truxima (rituximab-abbs) 10mg</td>
</tr>
<tr>
<td>Q5119</td>
<td>Injection, Ruxience (rituximab-pvvr) 10mg</td>
</tr>
</tbody>
</table>

LIMITATIONS/EXCLUSIONS:
Senior Care Options (Massachusetts Health Only-MHO) members.

RELATED REFERENCES:
6. [https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars](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 |

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