### Medical Necessity Guideline

<table>
<thead>
<tr>
<th>Medical Necessity Guideline (MNG) Title:</th>
<th>Select biologic agents</th>
</tr>
</thead>
<tbody>
<tr>
<td>MNG #: 015</td>
<td>☒ SCO ☒ One Care</td>
</tr>
<tr>
<td>Prior Authorization Needed?</td>
<td>☒ Yes ☐ No</td>
</tr>
<tr>
<td>Clinical: ☒</td>
<td>Operational: ☐</td>
</tr>
<tr>
<td>Medicare Benefit: ☒ Yes ☐ No</td>
<td>Approval Date: 5/14/2019;</td>
</tr>
<tr>
<td>Last Revised Date: 5/14/2019;</td>
<td>Next Annual Review Date: 5/19/2020;</td>
</tr>
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<td></td>
<td>Effective Date: 09/15/2019;</td>
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**OVERVIEW:**

Commonwealth Care Alliance requires the use of an InterQual SmartSheet to obtain prior authorization for the following biologic agents: pembrolizumab, rituximab, infliximab, IVIGs, omalizumab, botulinum toxins, vedolizumab, denosumab.

In order to obtain prior authorization for procedure(s), choose appropriate InterQual SmartSheet(s) listed below. The completed SmartSheet(s) must be submitted for prior authorization through the established process, in accordance with generally accepted clinical standards and the provider manual for authorization creation.

- Pembrolizumab
- Rituximab
- Infliximab
- Omalizumab
- OnabotulinumtoxinA (Botox, botulinum toxins)
- Vedolizumab
- Denosumab

**Rates:**

N/A

**DECISION GUIDELINES:**

**Clinical Eligibility:**

For IVIG, please choose IVIGs (Intravenous Immunoglobulin, general, lyophilized powder or general, non-lyophilized liquid; if necessary specify the name of the specific product you require).

To obtain InterQual® SmartSheets™

The following J codes should be used when submitting a request for PA for the specific biologic agent:

- J9271 - Pembrolizumab
- J9310 - Rituximab
- J1745 – Infliximab
- J2357 - Omalizumab
- J0587 - OnabotulinumtoxinA (Botox, botulinum toxins)
- J3380 - Vedolizumab
- J0897 - Denosumab
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Off-label Use Coverage for Other Diagnoses
Coverage for other diagnoses may be authorized provided effective treatment with such drug is recognized for treatment of such indication in one of the standard reference compendia, or in the medical literature, or other authoritative source as below.

CCA may authorize coverage for use for other cancer diagnoses provided effective treatment with such drug is recognized as a “Medically Accepted Indication” according to the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium as indicated by a Category 1 or 2A for quality of evidence and level of consensus.

Note: CCA requires prescribers to submit clinical documentation supporting the drug's effectiveness in treating the intended malignancy, including the applicable NCCN guideline(s) or another authoritative source.

In cases where the requested off-label use for the diagnosis is not recognized by the NCCN Drugs and Biologics Compendium, CCA will follow the Centers for Medicare and Medicaid Services (CMS) guidance, unless except as otherwise required, and accept clinical documentation referenced in one of the other “Standard Reference Compendia” noted below or supported by clinical research that appears in a regular (not supplemental) edition of a peer-reviewed medical journal with a print circulation. Requesting provider is required to submit full-text copies of supporting literature with the request.

LIMITATIONS/EXCLUSIONS:
N/A

KEY CARE PLANNING CONSIDERATIONS:
N/A

AUTHORIZATION:
N/A

REGULATORY NOTES:
N/A

RELATED REFERENCES:
"Standard Reference Compendia"
1. American Hospital Formulary Service – Drug Information (AHFS-DI)
2. Thomson Micromedex DrugDex
3. Clinical Pharmacology (Gold Standard)
4. Wolters Kluwer Lexi-Drugs
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ATTACHMENTS:

EXHIBIT A: 
EXHIBIT B: 

REVISION LOG:

<table>
<thead>
<tr>
<th>REVISION DATE</th>
<th>DESCRIPTION</th>
</tr>
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<tbody>
<tr>
<td>06/06/2019</td>
<td>MNG reviewed and passed by the Medical Policy Committee</td>
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APPROVALS:

Thomas A. Amoroso, MD  
CCA Senior Clinical Lead [Print]  
Title [Print]  
Signature  
06/06/2019  
Date

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CCA CMO or Designee [Print]  
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