Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Select biologic agents		
MNG #: 015	**☒SCO ☒One Care**	**Prior Authorization Needed?** **☒Yes ☐No**
Clinical: ☒	**Operational: ☐**	**Informational: ☐**
Medicare Benefit: **☒Yes ☐No**	**Approval Date:** 5/14/2019;	**Effective Date:** 9/15/2019;
Last Revised Date: 5/14/2019; 3/26/2020, 10/13/2020;	**Next Annual Review Date:** 5/19/2020; 3/26/2021; 10/13/2021;	**Retire Date:**

OVERVIEW:

Commonwealth Care Alliance requires the use of an InterQual® SmartSheets™to obtain prior authorization for the following biologic agents: pembrolizumab, rituximab, infliximab, IVIGs, omalizumab, botulinum toxins, vedolizumab, denosumab and ANY biologic therapeutic which does not have its own separate Medical Necessity Guideline (MNG) for indications and approval.

In order to obtain prior authorization for procedure(s), choose the 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
- Biologic (other)

For biologic agents that belong to a specific class that has a CCA preferred biosimilar, this MNG applies to both the preferred and non-preferred biologic agent. For Step Therapy requirements for non-preferred medical benefit injectables where preferred biosimilars are available, refer to MNG 040 Medicare Part B Step Therapy.

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:

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- J9271 - Pembrolizumab
- J9310 - Rituximab
- J1745 – Infliximab
- J2357 - Omalizumab
- J0587 - OnabotulinumtoxinA (Botox, botulinum toxins)
- J3380 - VedolizumabJ0897 - Denosumab

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 ofconsensus.

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

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:

"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

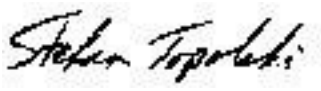
ATTACHMENTS:

EXHIBIT A:	
EXHIBIT B:	

REVISION LOG:

REVISION DATE	DESCRIPTION
06/06/2019	MNG reviewed and passed by the Medical Policy Committee
3/26/2020	KH staff updated document.
10/13/2020	Updated document

APPROVALS:

Stefan Topolski, MD	Medical Director, Medical Affairs
CCA Senior Clinical Lead [Print]	**Title [Print]**
	3/26/2020
Signature	**Date**
CCA Senior Operational Lead [Print]	**Title [Print]**
Signature	**Date**

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Lori Tishler, MD	Senior Vice President, Medical Services
CCA CMO or Designee [Print]	**Title [Print]**
	06/06/2019
Signature	**Date**